DIRECTIVE 2014/68/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

2014 / 68 /EU 指令

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on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment

依据各成员国有关法律统一制作，适用于压力设备市场

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof, having regard to the proposal from the European Commission, after transmission of the draft legislative act to the national parliaments, having regard to the opinion of the European Economic and Social Committee, Acting in accordance with the ordinary legislative procedure
欧洲议会和欧盟理事会，
根据欧盟运作条约，特别是第 114 条款，考虑到来自欧洲委员会的建议，将立法法案草案传给国家议会后，根据欧洲经济和社会委员会的意见，按照普通立法程序，

Whereas:
鉴于：

(1) Directive 97/23/EC of the European Parliament and of the Council has been substantially amended. Since further amendments are to be made, that Directive should be recast in the interests of clarity.
（1）欧洲议会和理事会的 97/23/EC 指令已大幅修订。既然进一步的修订需要作出，该指令需要重新制定，以清晰说明。

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
（2）欧洲议会和理事会条例(EC) No 765/2008 制定了有关合格评定机构认可的规则，为产品的市场监管及来自第三国家的产品控制提供了一个框架，并规定了 CE 标识的总则。

(3) Decision No 768/2008/EC of the European Parliament and of the Council (6) lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 97/23/EC should therefore be adapted to that Decision.
（3）根据欧洲议会和理事会第 768/2008/EC 决议，规定了了共同的原则和旨在适用于部门立法的参考条款，为立法提供统一的修订或重新制定基础。因此 97/23/EC 指令亦应符合这一决议。

(4) This Directive covers pressure equipment and assemblies which are new to the Union market when they are placed on the market; that is to say they are either new pressure equipment or assemblies made by a manufacturer established in the Union or pressure equipment or assemblies, whether new or second-hand, imported from a third country.

（4）本指令包含了新投入欧盟市场的压力设备和组件，也就是说，他们或是一个新的压力设备或由欧盟制造商所组装的组件，或是从第三国进口的压力设备和组件，无论是新设备还是二手的。

(5) This Directive should apply to all forms of supply, including distance selling.
（5）本指令适用于包括远程销售的所有形式供应。

(6) This Directive should apply to pressure equipment subject to a maximum allowable pressure PS greater than 0.5 bar. Pressure equipment subject to a pressure of not more than 0,5 bar does not pose a significant risk due to pressure. Therefore, there should not be any obstacle to its free movement within the Union.
（6）本指令应适用于最大允许压力（PS）大于 0.5 Bar 的压力设备。最大允许压力不超过 0.5 Bar 的压力设备不存在重大压力风险。因此，此类产品在欧盟内自由流通不应该有任何阻碍。

(7) This Directive should also apply to assemblies composed of several pieces of pressure equipment assembled to constitute an integrated and functional whole. Those assemblies may range from simple assemblies such as pressure cookers to complex assemblies such as water tube boilers. If the manufacturer of an assembly intends to place it on the market and put it into service as an assembly — and not in the form of its constituent non- assembled elements — that assembly should comply with this Directive. However, this Directive should not apply to the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer, as in the case of industrial installations.
（7）本指令也适用于由几件压力设备组装成的，构成一个功能整体的组合件。这些组合件从简单组合件（如压力锅）到复杂组合件（如水管锅炉）。如果组合件的制造商计划将它作为组合件（作为一个整体，而不是以组成部分的形式）投入市场，该组合件也应符合本指令。但是，该指令不适用于如工业建造情形下的现场压力设备装配，也不适用由于不是制造商的使用者。

(8) This Directive should harmonise national provisions on risks due to pressure. The other risks which this equipment may present may fall within the scope of other Directives dealing with those risks.
（8）本指令应符合国家规定的压力产生的风险。本产品所面临的其他风险可能属于其他处理这些风险指令的范围。

(9) However, some pressure equipment is covered by other Directives based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). The provisions laid down in some of those Directives deal also with the risk due to pressure. Those Directives are considered adequate to provide appropriate protection where the risk due to pressure associated with such equipment remains small. Therefore, such equipment should be excluded from the scope of this Directive.
（9）然而，一些压力设备属于根据欧盟运作条约（TFEU）第 114 条运作的其他指令。在这些指令中也规定了处理由于压力产生的风险。由于涉及到这些设备的压力很小，可以认为这些指令足以对压力风险提供适当的保护。因此，这类设备应排除在本指令范围内。

(10) For some pressure equipment covered by international agreements for its international transport, national transport and pressure hazards and risks are dealt with by Union Directives based on such agreements. Those Directives extend the application of those agreements to national transport, in order to ensure the free movement of dangerous goods whilst enhancing transport safety. Such equipment which is covered by Directive 2008/68/EC of the European Parliament and of the Council and by Directive 2010/35/EU of the European Parliament and of the Council should be excluded from the scope of this Directive.
（10）对于一些由于国际或国内运输，压力风险已经被国际协议所涵盖的压力设备，欧盟指令依照国际协议进行。这些指令将这些协议的应用扩展到国内运输，确保危险货物的自由流动的同时提高运输安全。因此，那些依据欧洲议会和理事会 2008/68/EC 和 2010/35/EU 指令所覆盖的设备应排除在本指令的范围内。

(11) Certain types of pressure equipment, although subject to a maximum allowable pressure PS greater than 0,5 bar, do not present any significant risk due to pressure, and therefore the free movement of such equipment in the Union should not be hindered if it has been legally manufactured or placed on the market in a Member State. It is not necessary in order to ensure free movement of such equipment to include it within the scope of this Directive. Consequently it should be expressly excluded from its scope.
（11）某些类型的压力设备，虽然受到最大允许压力 PS 大于 0.5 Bar，但不存在任何显著的压力风险，如果它已在成员国内被合法的制造或投入市场，这种设备在欧盟内的自由流通不应被阻碍。为确保这些设备的自由流通而将之包涵在本指令的范围内是没有必要的。因此，它应该被明确排除在其范围内。

(12) Other pressure equipment subject to a maximum allowable pressure greater than 0,5 bar and presenting a significant risk due to pressure, but in respect of which free movement and an appropriate level of safety are guaranteed, should be excluded from the scope of this Directive. Such exclusions should, however, be regularly reviewed in order to ascertain whether it is necessary to take action at Union level.
（12）其他最大允许压力大于 0.5 Bar 且存在显著压力风险的压力设备，但考虑到在市场上自由流通和适当等级的安全是有保证的，应排除在本指令范围之外。这样的除外需要定期审议，以确定是否有必要在欧盟等级采取行动。

(13) The scope of this Directive should be based on a general definition of the term ‘pressure equipment’ so as to allow for the technical development of products.
（13）本指令范围应根据术语“压力设备”的一般定义，以便产品的技术开发。

(14) Compliance with the essential safety requirements is necessary in order to ensure the safety of pressure equipment. Those requirements should be subdivided into general and specific requirements that need to be met by pressure equipment. In particular the specific requirements should take account of particular types of pressure equipment. Certain types of pressure equipment in categories III and IV should be subject to a final assessment comprising final inspection and proof tests.
（14）为确保压力设备的安全，遵守基本安全要求是必要的。这些要求应分为压力设备应满

足的一般和特殊的要求，特别应考虑特定类型压力设备的特殊要求。在 Categories III 和 Categories IV 中，某些类型的压力设备应进行包括最终检验和验证试验的最终评定。

(15) Member States should be in a position to allow the showing at trade fairs of pressure equipment which is not yet in conformity with the requirements of this Directive. During demonstrations, appropriate safety measures should be taken in accordance with the general safety rules of the Member State concerned to ensure the safety of persons.
（15）欧盟会员国应允许在贸易展会上展示尚未符合本指令要求的压力设备。在展示过程中，应按照成员国的基本安全法规，采取适当的安全措施，确保人员安全。

(16) Directive 97/23/EC provides for a classification of pressure equipment in categories, according to the ascending level of hazard. This includes the classification of the fluid contained in the pressure equipment as dangerous or not, according to Council Directive 67/548/EEC. On 1 June 2015 Directive 67/548/EEC is to be repealed and replaced by Regulation (EC) No 1272/2008 of the European Parliament and of the Council, which implements in the Union the Globally Harmonised System of Classification and Labelling of Chemicals that has been adopted at international level, within the United Nations structure. Regulation (EC) No 1272/2008 introduces new hazard classes and categories only partially corresponding to those provided for by Directive 67/548/EEC. Directive 97/23/EC should therefore be aligned to Regulation (EC) No 1272/2008 while maintaining the existing levels of protection provided for in that Directive.
（16）97/23/EC 指令提供了一个压力设备依据危险等级类别分类的方法。该分类攘括了理事会 67/548/EEC 指令对于压力设备中的流体是否危险的分类方法。2015 年 6 月 1 日，67/548/EEC 指令被废除并被欧洲议会和理事会 No 1272/2008 法规取代，实现了欧盟统一的全球性化学品分类和标签，并在联合国框架内被国际所接受。No 1272/2008 法规加入了新的危险等级和危险品品类，对应于指令 67/548/EEC 的内容。因此 97/23/EC 指令应该与 No 1272/2008 法规保持一致，维持目前指令规定的保护等级。

(17) Economic operators should be responsible for the compliance of pressure equipment and assemblies with the requirements of this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons, and the protection of domestic animals and of property, and to guarantee fair competition on the Union market.
（17）压力设备及其组合件的经营者应依据他们各自在供应链中的角色，负责产品符合本指令的要求，从而可以高水平保护如人员健康和安全的公共利益，保护国内动物和财产以及保证欧盟市场的公平竞争。

(18) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market pressure equipment and assemblies which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
（18）所有在供应和经销链中的经营者应采取适当的措施，确保他们只投放符合此指令的压力设备和组合件进入市场。依据每个经销商在供应及经销链中的作用，有必要提供一个明确的按比例分配的义务。

(19) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
（19）具有设计和生产过程细节知识的制造商是进行合格评定程序的最佳选择。因此，合格评定应仅针对制造商。

(20) In order to facilitate the communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
（20）为方便经营者、市场监管机构及消费者沟通，成员国应鼓励运营商除了邮政地址还应提供一个网站地址。

(21) It is necessary to ensure that pressure equipment and assemblies from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that pressure equipment or those assemblies. Provision should therefore be made for importers to make sure that the pressure equipment or assembly they place on the market complies with the requirements of this Directive and that they do not place on the market pressure equipment or assemblies which do not comply with such requirements or presents a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that marking of pressure equipment or assemblies and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
（21）必须确保进入欧盟市场的第三国压力设备与组合件符合本指令的要求，特别是对那些需要制造商进行合适的合格评定程序的压力设备或组合件。因此，应针对进口商制定法规，确保他们投放在市场上的压力设备或组合件符合本指令的要求，他们不得投放不满足要求或带有风险的压力设备或组合件。也应为进口商制定法规，确保合格评定程序可以实施，制造商制定的压力设备或部件的名牌和文件可供国家有关部门检验。

(22) When placing pressure equipment or assemblies on the market, every importer should indicate on the pressure equipment or assembly his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the pressure equipment or assembly does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the pressure equipment or assembly.
（22）当在市场上投放压力设备或组合件时，除非压力设备或组合件的大小或自然条件不允许，进口商应在压力设备或组合件上标明它的名称、注册品牌名称或注册商标和可供联系的邮政地址。这也包含进口商需要打开包装，将名称和地址印在压力设备或组合件上的情形。

(23) The distributor makes pressure equipment or assemblies available on the market after they have been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the pressure equipment or assembly does not adversely affect the compliance of the pressure equipment or assembly with the requirements of this Directive.

（23）在制造商或进口商将压力设备或组合件投放市场后，经销商才可以让设备在市场流通，并应小心确保对该压力设备或组合件的处理不会影响该设备满足本指令要求。

(24) Any economic operator that either places pressure equipment or assemblies on the market under his own name or trademark or modifies pressure equipment or assemblies in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
（24）任何以自己的名义或商标将压力设备或组合件投放市场，或是修改压力设备或组合件，可能会影响产品符合本指令要求的运营商，应被视为制造商并承担制造商的义务。

(25) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the pressure equipment or assembly concerned.
（25）靠近市场的经销商和进口商，应积极参与由国家相关主管部门进行的市场监管任务，向当局提供压力设备或组合件的所有相关必要信息。

(26) Ensuring traceability of pressure equipment and assemblies throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant pressure equipment or assemblies available on the market.
（26）确保压力设备和组合件在整个供应链中的可追溯性有助于使市场监管更为简单、有效。一个有效的追溯系统有助于市场监管机构的任务，以追踪向市场投放不符合标准的压力设备或组合件的运营商。

(27) When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with pressure equipment or an assembly or to whom they have supplied pressure equipment or an assembly.
（27）除提供本指令所要求的为其他经营者识别的资料情况外，不应要求经营者更新这些资料给其他经营者，包括谁为他们提供压力设备或组合件，或他们为谁提供压力设备或组合件。

(28) This Directive should be limited to the expression of the essential safety requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for pressure equipment or assemblies which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council for the purpose of expressing detailed technical specifications of those requirements, especially with regard to the design, manufacture and testing of pressure equipment or assemblies.
（28）本指令应仅限于基本安全要求的表述。为了方便依据要求进行合格评定，需要为压力设备或组合件提供合格推定，推定那些设备满足欧洲议会和理事会(EU) No 1025/2012 对应的标准。(EU) No 1025/2012 法规详细阐明了压力设备或组合件的技术规范要求，尤其针对设备的设计、制造和测试环节。

(29) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
（29）(EU) No 1025/2012 法规为设备满足相关标准提供了一个程序，尽管那些标准不完全满足本指令的要求。

(30) Manufacturing of pressure equipment calls for the utilisation of safe materials. In the absence of harmonised standards the characteristics of the materials intended for repeated use should be established. Those characteristics should be established by European approvals for materials, such approvals being issued by one of the notified bodies specifically designated for that task. The materials conforming to the European approvals should benefit from a presumption of conformity with the essential safety requirements of this Directive.
（30）压力设备的制造要求使用安全材料。在缺乏相应标准时，应建立重复使用材料的性能指标。这些材料性能指标的建立应由欧盟批准。此类批准应由一个通告机构（notified body）专门为该任务发出。符合欧盟批准的材料应从本指令基本安全要求的合格推定中受益。

(31) In view of the nature of the risks involved in the use of pressure equipment and assemblies and in order to enable economic operators to demonstrate and the competent authorities to ensure that pressure equipment or assemblies made available on the market comply with the essential safety requirements, it is necessary to provide for conformity assessment procedures. Those procedures should be devised in the light of the level of hazard which is inherent in the pressure equipment or assembly. Therefore, for each category of pressure equipment there should be an adequate procedure or a choice between different procedures of equivalent stringency. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. The details added to those procedures are justified by the nature of the verification required for pressure equipment.
（31）考虑到压力设备和组合件的使用风险，同时让运营商展示，以及让主管当局确保市场上的压力设备或组合件符合基本安全要求，有必要提供相应的合格评定程序。这些程序应按压力设备或组合件固有的危险等级划分等级。因此，对每一类压力设备应该有一个适当的程序或可以等效选择不同的程序。No 768/2008/EC 决议依据设备所涉及的风险水平和所需的安全要求，建立了从最基本到最严格的模块化合格评定程序。为确保各部分的连贯，并避免特例，合格评定程序应在这些模块间选择。这些程序加入的细节是为了验证压力设备所需的。

(32) Member States should be in a position to authorise user inspectorates to carry out certain tasks for conformity assessment in the framework of this Directive. For that purpose this Directive should set out criteria for the authorisation of user inspectorates by Member States.
（32）成员国应授权用户监察部门以本指令为框架进行合格评定。为了这个目的，本指令应由成员国授权，以保证用户监察部门的权威性。

(33) Under certain procedures for conformity assessment it should be possible for each item to be inspected and tested by a notified body or a user inspectorate as part of the final assessment of the pressure equipment or assembly. In other cases provision should be made to ensure that

the final assessment may be monitored by a notified body by means of unexpected visits.
（33）在某些合格评定程序中，作为压力设备或组合件最终评定的一部分，可能由公告机构（Notified Body，如阿拜维 APAVE）或用户检验机构对每一个项目进行检查和测试。在其他情况下应作出规定，以确保公告机构（Notified Body，如阿拜维 APAVE）可以对最终评定进行不定期突击访问。

(34) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of the pressure equipment or assembly with the requirements of this Directive and of other relevant Union harmonisation legislation.
（34）制造商应拟定欧盟符合性声明，提供本指令要求的相关信息，以保证压力设备或组合件符合本指令或其他欧盟相关法令。

(35) To ensure effective access to information for market surveillance purposes, in cases where pressure equipment or an assembly is covered by several pieces of Union harmonisation legislation, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
（35）当压力设备或组合件被多个欧盟相关法令所覆盖时，为进行市场监管，应保证可以有效获取信息，欧盟符合性声明内的信息应包含所有适用的欧盟法规。为减少对运营者的行政负担，单个欧盟符合性声明可由许多相关的符合性声明档案组成。

(36) A check on compliance with the essential safety requirements is necessary in order to provide effective protection for consumers, other users and third parties.
（36）有必要根据基本安全要求进行检查，以对消费者、其他用户和第三方提供有效保护。

(37) Pressure equipment and assemblies should, as a general rule, bear the CE marking. The CE marking, indicating the conformity of pressure equipment or assemblies, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
（37）一般来说，压力设备和组合件应标记 CE 标识。表明压力设备或组合件符合要求的 CE 标识是表明整个广义合格评定过程的可见结果。在(EC) No 765/2008 法规中阐述了 CE 标识的一般原则及与其他标识关系。在这个指令中规定了粘贴 CE 标识的要求。

(38) For pressure equipment defined in this Directive which presents only a minor pressure risk and for which certification procedures are therefore not justified, the CE marking should not be affixed.
（38）对于本指令中定义的只具有轻微压力风险的压力设备，或未规定认证程序的设备，不应在设备上粘贴 CE 标识。

(39) Certain conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

（39）本指令规定的某些合格评定程序需要由各成员国向委员会公告的合格评定机构参与。

(40) Experience has shown that the criteria set out in Directive 97/23/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of those bodies throughout the Union. It is, however, essential that all conformity assessment bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
（40）经验表明，97/23/EC 指令设定的合格评定机构必须满足，以获得委员会公告的准则不足以保证整个欧盟机构具有相同的高水平表现。然而，必须保证所有合格评定机构在相同水平及公平竞争的条件下发挥它们的职能。这需要为那些希望得到公告，以提供合格评定服务的合格评定机构设立强制性要求。

(41) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
（41）如果合格评定机构表明符合相关标准设立的准则，应推定符合本指令设立的相应要求。

(42) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of conformity assessment bodies.
（42）为了保证合格评定质量水平一致，有必要也对公告主管和其他参与评定、公告和监督的评定机构提出要求。

(43) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
（43）本指令使用的体系应由 No 765/2008 法规提供的认可体系所补充。既然认可是一种验证整个公告机构能力的重要手段，也应在公告时使用。

(44) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
（44）No 765/2008 法规提供透明的认可，保证合格证书有信心达到的水平，欧盟各地公共机构应考虑将之作为体现合格评定机构技术能力的首选方法。然而，国家机构可能会认为自己可以通过适当手段评定自己。在这种情况下，为确保与其他国家机构评定的要求相同，他

们应该向委员会和其他成员国提供必要的文献证据，以证明符合评定机构有关监管要求。

(45) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the pressure equipment or assembly to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
（45）合格评定机构经常分包部分与合格评定有关的项目或依靠附属机构。为了保障投入欧盟市场的压力设备或组合件的保护能力，有必要针对分包商和附属机构进行与公告机构（Notified Body，如阿拜维 APAVE）相同的合格评定工作。因此，评定将被公告的机构能力和表现和监控已公告的机构时，同时涵盖评价其分包商及附属公司所进行的活动十分重要。

(46) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
（46）有必要提高公告程序的效率和透明度，特别是运用新技术，如网上公告。

(47) Since conformity assessment bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
（47）由于合格评定机构可在整个欧盟提供服务，其他成员国和委员会可以对该公告机构（Notified Body，如阿拜维 APAVE）提出反对意见。因此，合格评定机构在成为公告机构（Notified Body，如阿拜维 APAVE）之前，可以获得一个时限来澄清任何疑虑是非常重要的。

(48) In the interests of competitiveness, it is crucial that conformity assessment bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between conformity assessment bodies.
（48）在利益竞争中，合格评定机构合格评定过程中没有为经营者创造不必要的负担是至关重要的。同样的，为确保经营者的平等待遇，需要保证合格评定程序中技术申请的一致性。合格评定机构之间最好能保证适当的协调和合作。

(49) Member States should take all appropriate measures to ensure that pressure equipment and assemblies may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Pressure equipment or assemblies should be considered as non-compliant with the essential safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could

result from lawful and readily predictable human behaviour.
（49）各成员国应采取一切适当的措施，确保压力设备和组合件仅可能在妥善存储、用于预定目的、或在可以合理预见的、不危及人健康和安全的条件下被投入市场。压力设备或组合件，只能在合法的、容易合理预见的情况下使用，其余情况都应被视为不符合本指令基本安全规定。

(50) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred to the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.
（50）为确保本指令的统一实施，委员会被授予应相应的执行权。应依照欧盟 No 182/2011 规定实施这些权力。

(51) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
（51）对于不符合或不再符合公告要求的公告机构（Notified Body，如阿拜维 APAVE），公告成员国应采取咨询程序，实施必要的纠正措施。

(52) The examination procedure should be used for the adoption of implementing acts with respect to European approvals for materials presenting shortcomings and whose references were already published in the Official Journal of the European Union, given that such decisions could have consequences on the presumption of conformity with the applicable essential requirements.
（52）考虑到欧盟批准材料的短缺而采纳执行法规，需要进行审查程序，或参考已在欧盟官方杂志公布的（材料），作出该决定将假定符合适用的基本要求。

(53) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant pressure equipment or assemblies which present a risk to the health or safety of persons, to domestic animals or to property, imperative grounds of urgency so require.
（53）在涉及压力设备或组合件危及人的健康或安全、或对国内生物或财产有风险、必要且迫切理由等这样正当理由的情况下，委员会应立即采取恰当的行动。

(54) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
（54）依据既定程序，考虑到该指令是由委员会主席或成员国的代表按照其程序规定实施，该指令委员会可以在审核事项方面发挥重要作用。

(55) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
（55）除了实施或违反本指令，当有关本指令的事务被（如：一个委员会专家小组）核查时，

欧洲议会应按现有的程序，获得充分的信息和资料，并在适当的情况下被邀请参加会议。

(56) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant pressure equipment or assemblies are justified or not.
（56）委员会应通过立法规定，给予他们特殊的、不受(EU) No 182/2011 法规约束的权利，用以裁定成员国关于该指令不适用压力设备或组合件的评定方法是否合理。

(57) In order to take into account emerging very serious safety reasons, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amendments to classification of pressure equipment or assemblies. The reclassification should be based on appropriate evidence and justification in each case. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
（57）考虑到出现非常严重的安全情况，根据 TFEU 第 290 条，应授予委员会修订压力设备或组合件类别的权力。重新分类应根据每个案例合适的证据和理由确定。在委员会（包括专家级别）筹备期间，适当的磋商工作尤其重要。

(58) The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
（58）委员会在准备和制定授权法规时，应确保通过适当的方式，同时且及时地向欧洲议会和理事会传递有关文件。

(59) Directive 97/23/EC provides for a transitional arrangement enabling pressure equipment and assemblies which comply with the national regulations in force on the date of application of Directive 97/23/EC to be put into service. For reasons of legal certainty, it is necessary to include that transitional arrangement also in this Directive.
（59）97/23/EC 指令提供了一个过渡期，让符合国家规定的压力设备和组合件在 97/23/EC 指令生效时强制满足要求。出于法律上确定的原因，该指令也有必要设立过渡期。

(60) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and the putting into service, without the need to comply with further product requirements, of pressure equipment and assemblies that have already been placed on the market in accordance with Directive 97/23/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply pressure equipment and assemblies that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.
（60）有必要为，已经满足 97/23/EC 指令，并已在市场上使用和投放的压力设备和组合件，提供合理的过渡性安排，而不需要该设备符合更多的产品要求。因此，在国家实施该指令之前，经销商应能提供已投放在市场上的压力设备和组合件清单，即已经在市场经销链中的库存。

(61) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
（61）成员国应根据本指令，制定适用本国家法律规定的侵权行为处罚规定，并确保这些法规实施。规定的处罚应有效，适当和劝诫性的。

(62) Since the objective of this Directive, namely to ensure that pressure equipment or assemblies on the market fulfil the requirements providing a high level of protection of health and safety of persons and protection of domestic animals or property while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
（62）该指令目的在于确保市场上的压力设备或组合件满足提供高水平人员健康和安全保护，以及保障国内动物或财产的要求，同时保证成员国内部市场不能充分实现的，或更确切地说，考虑到规模和效果，从欧盟层面可以更好实现的功能。欧盟将可能会按照欧盟条约第 5 条中规定的辅助性为原则，采取相应措施。根据第 5 条款确定的比例原则，该指令没有使用超过必要的手段来实现这一目标。

(63) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
（63）将该指令纳入国家法律的义务应区别于以前指令的实质性修订的规定。转变规定的义务同样在之前指令提及。

(64) This Directive should be without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and the date of application of the Directive set out in Annex V, Part B,
（64）该指令应不影响成员国根据时间限制将该指令设立为国家法律，指令实施日期载于附录 V 的 B 部分，

HAVE ADOPTED THIS DIRECTIVE:
已采纳该指令：

CHAPTER 1
GENERAL PROVISIONS
第1章　一般规定

Article 1
第 1 条
Scope
范围

1. This Directive shall apply to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar.
1．本指令应适用于最大允许压力 PS 大于 0.5 Bar 的压力设备及组合件的设计、制造和合格评定。

2. This Directive shall not apply to:
2、本指令不适用于：

(a) pipelines comprising piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore) starting from and including the last isolation device located within the confines of the installation, including all the annexed equipment designed specifically for pipelines; this exclusion shall not apply to standard pressure equipment such as may be found in pressure reduction stations or compression stations;
（a）设计用于从或向一个站点（陆地或近海）输送流体或物质的管道或管道系统组成的、从最后的隔离装置起的管线，包括专门为管线设计的所有附加设备。但该例外不包括在减压站或压缩站所见到的标准承压设备。

(b) networks for the supply, distribution and discharge of water and associated equipment and headraces such as penstocks, pressure tunnels, pressure shafts for hydroelectric installations and their related specific accessories;
（b）为供应、分配和排放水的网络及其相关设备，以及水电装置用的如进水管、压力管道、水电设施的压力轴及其相关专用配件；

(c) simple pressure vessels covered by Directive 2014/29/EU of the European Parliament and of the Council;
（c）由欧洲议会和理事会 2014/29/EU 指令所涵盖的简单压力容器；

(d) aerosol dispensers covered by Council Directive 75/324/EEC ;
（d）由理事会 75/324/EEC 指令所涵盖的气溶胶分配器；

(e) equipment intended for the functioning of vehicles defined by the following legal acts:
（e）用于下列法律定义车辆功能的设备：

(i) Directive 2007/46/EC of the European Parliament and of the Council;
（i）欧洲议会和理事会 2007/46/EC 指令；
(ii) Regulation (EU) No 167/2013 of the European Parliament and of the Council (1);
（ii）欧洲议会和理事会 No 167/2013 法规；
(iii) Regulation (EU) No 168/2013 of the European Parliament and of the Council (2);
（iii）欧洲议会和理事会 No 168/2013 法规；

(f) equipment classified as no higher than category I under Article 13 of this Directive and covered by one of the following Directives:
（f）分类为不高于本指令第 13 条第 I 类，并被以下其中一个指令涵盖的设备：
(i) Directive 2006/42/EC of the European Parliament and of the Council;
（i）欧洲议会和理事会 2006/42/EC 指令；
(ii) Directive 2014/33/EU of the European Parliament and of the Council;
（ii）欧洲议会和理事会 2014/33/EU 指令；
(iii) Directive 2014/35/EU of the European Parliament and of the Council;
（ii）欧洲议会和理事会 2014/35/EU 指令；
(iv) Council Directive93/42/EEC;
（iv）理事会 93/42/EEC 指令；
(v) Directive 2009/142/EC of the European Parliament and of the Council;
（v）欧洲议会和理事会 2009/142/EC 指令；
(vi) Directive 2014/34/EU of the European Parliament and of the Council;
（vi）欧洲议会和理事会 2014/34/EU 指令；

(g) equipment covered by point (b) of Article 346 TFEU;
（g）TFEU 第 346 条第（b）款所涵盖的设备；

(h) items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;
（h）专为核用途而设计，可能会导致放射性物质排放的设备；

(i) well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure; this shall comprise the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;
（i）石油、天然气或地热勘探、开采业的井控设备，和为了包含和/或控制井压力地下储藏容器。这将包括井控装置（采油树），吹出阀（BOP），管道歧管和他们所有的井上设备；

(j) equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor; such equipment may include:
（J）包括套管或机械的设备，该类设备的尺寸、材料和制造规则主要根据要求定义，需要有足够的强度、刚度和稳定性，以满足静态和动态的操作效果或其他操作特性，压力不是一个特别的设计因素，设备可能包括：

(i) engines including turbines and internal combustion engines;
（i）发动机，包括涡轮机和内燃机；
(ii) steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;
（ii）蒸汽机，燃气/蒸汽涡轮机，涡轮发电机，压缩机，泵和致动装置；

(k) blast furnaces including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust- gas scrubbers and direct reducing cupolas, including the furnace cooling, gas converters and pans for melting, re- melting, de-gassing and casting of steel, iron and non-ferrous metals;
（k）鼓风炉，包括炉体冷却系统、热风换热器、除尘器、高炉尾气—气体洗涤器和直接还原炉，包括炉体冷却，气转换器以及熔化、再熔化、脱气、铸造钢、铁或有色金属用的锅炉；

(l) enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;
（l）用于高压电器设备的外壳，如开关设备、控制装置、变压器和旋转机器;

(m) pressurised pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;
（m）压力管道输送系统的容器，例如电力和电话线；

(n) ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof;
（n）船舶、火箭、飞机和可移动离岸单位，以及专门用于安装在船上或其推进的设备；

(o) pressure equipment consisting of a flexible casing, e.g. tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;
（o）压力设备组成的可拆卸外壳，如轮胎，空气垫，用于玩耍的球，充气船和其他类似压力设备；

(p) exhaust and inlet silencers;
（p）进、排气消声器；

(q) bottles or cans for carbonated drinks for final consumption;
（q）用于最终消费的碳酸饮料瓶或罐；

(r) vessels designed for the transport and distribution of drinks having a PS.V of not more than 500 bar.L and a maximum allowable pressure not exceeding 7 bar;
（r）专为饮料输送和分装设计的容器，PS*V 不超过 500 bar*L，并且最大允许压力不超过 7 bar；

(s) equipment covered by Directive 2008/68/EC and Directive 2010/35/EU and equipment covered by the International Maritime Dangerous Goods Code and the Convention on International Civil Aviation;

（s）由 2008/68/EC 指令和 2010/35/EU 指令涵盖的设备和国际海上危险品法典与国际民用航空公约设备所覆盖的设备；

(t) radiators and pipes in warm water heating systems;
（t）在温水加热系统中的散热器和水管；

(u) vessels designed to contain liquids with a gas pressure above the liquid of not more than 0,5 bar.
（u）设计包含液体与气体压力的液体上面不超过 0.5 Bar 的容器。

Article 2
第 2 条
Definitions
定义

For the purposes of this Directive, the following definitions shall apply:
依据本指令的目的，适用以下定义：

(1) 'pressure equipment' means vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs;
（1）"压力设备"是指容器、管道、安全附件及压力附件；在适用时也包括加在压力设备上的部件，如法兰、喷嘴、接头、支架、吊耳；

(2) 'vessel' means a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment; a vessel may be composed of more than one chamber;
（2）容器"是指设计和制造装载压力流体的壳体，包括与其它设备相连连接点的直接连接件。一个容器可由一个以上腔体组成；

(3) 'piping' means piping components intended for the transport of fluids, when connected together for integration into a pressure system; piping includes in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressure-bearing components as appropriate; heat exchangers consisting of pipes for the purpose of cooling or heating air shall be considered as piping;
（3）"管道"是指用于输送流体的管道元件，联结成一个压力系统。管道特别包括管道或管道系统、管子、管路附件、膨胀节、软管或其它承压元件。由管子组成的用于冷却或加热空气的热交换器可视为管道。

(4) 'safety accessories' means devices designed to protect pressure equipment against the allowable limits being exceeded, including devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and limiting devices, which either activate the means for correction or provide for shutdown or shutdown and lockout, such as pressure switches or temperature switches or fluid

level switches and safety related measurement control and regulation (SRMCR) devices;
（4）“安全附件”是指被设计用于防止压力设备超出允许极限的装置。这类装置包括：
——直接限制压力的装置，如安全阀、爆破膜装置、受控的安全释放系统（CSPRS），
——限制装置，既有触发更正的装置也有提供关闭或锁闭的装置，如压度开关、液位开关与安全有关的控制和调节（SRMCR）装置。

(5) ‘pressure accessories’ means devices with an operational function and having pressure-bearing housings;
（5）“压力附件”是指具有操作功能和承压的壳体；

(6) ‘assemblies’ means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;
（6）“组合件”是指制造商将几个承压设备组装成一个整体的功能件。

(7) ‘pressure’ means pressure relative to atmospheric pressure, i.e. gauge pressure. As a consequence, vacuum is designated by a negative value;
（7）“压力”是指相对于大气压的压力，即表压。因此真空用负值来表示。

(8) ‘maximum allowable pressure PS’ means the maximum pressure for which the equipment is designed, as specified by the manufacturer, and defined at a location specified by him, being either the connection of protective and/or limiting devices, or the top of equipment or, if not appropriate, any point specified;
（8）“最大允许压力 PS”是指制造商在设计设备时规定的最大压力。它限定在制造商指定位置。在保护和/或限制装置的连接处或设备顶部，如果都不合适，则为某一指定的点。

(9) ‘maximum/minimum allowable temperature TS’ means the maximum/minimum temperatures for which the equipment is designed, as specified by the manufacturer;
（9）“最大/最小允许温度”是指制造商在设计设备时规定的最大/最小允许温度。

(10) ‘volume (V)’ means the internal volume of a chamber, including the volume of nozzles to the first connection or weld and excluding the volume of permanent internal parts;
（10）“容积 V”是指腔体内部的体积，包括至第一个连接或焊缝处接管的体积，但不包括永久性联接件内的体积。

(11) ‘nominal size (DN)’ means a numerical designation of size which is common to all components in a piping system other than components indicated by outside diameters or by thread size; it is a convenient round number for reference purposes and is only loosely related to manufacturing dimensions; the nominal size is designated by DN followed by a number;
（11）“公称尺寸（DN）”是指设计的尺寸数值，通指一个管道系统的所有零件，不是用外径和螺纹尺寸表示元件的尺寸。它是用作参考的整数，仅与制造尺寸松散关联。公称尺寸用 DN 后面加一数字表示。

(12) ‘fluids’ means gases, liquids and vapours in pure phase as well as mixtures thereof; fluids may contain a suspension of solids;

（12）“流体”是指单相的气体、液体或蒸气及它们的混合物。流体可含有固体悬浮物。

(13) ‘permanent joints’ means joints which cannot be disconnected except by destructive methods;
（13）“永久性连接”是指只有通过破坏方式才能分开的连接；

(14) ‘European approval for materials’ means a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment which are not covered by any harmonised standard;
（14）“欧洲材料批准”是指制造压力设备时，对未被协调标准所含盖且打算反复使用材料的特性进行规定的技术文件。

(15) ‘making available on the market’ means any supply of pressure equipment or assemblies for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
（15）“市场流通”指任何在欧盟市场上提供压力设备或组合件经销或使用的商业活动过程，无论是有偿或是免费；

(16) ‘placing on the market’ means the first making available of pressure equipment or assemblies on the Union market;
（16）“投放市场”指压力设备或组合件第一次投放在欧盟市场；

(17) ‘putting into service’ means the first use of pressure equipment or an assembly by its user;
（17）“投入使用”指用户第一次使用压力设备或组合件；

(18) ‘manufacturer’ means any natural or legal person who manufactures pressure equipment or an assembly or has such equipment or assembly designed or manufactured, and markets that pressure equipment or assembly under his name or trademark or uses it for his own purposes;
（18）“制造商”指任何制造压力设备或组合件，或曾经设计或制造这类设备或组合件，以及将压力设备或组合件之名义或品牌投放市场，或自己使用的自然人或法人；

(19) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
（19）“授权代表”指任何在欧盟内设立的已收到制造商书面授权，代表制造商行使某些任务的自然人或法人；

(20) ‘importer’ means any natural or legal person established within the Union who places pressure equipment or assemblies from a third country on the Union market;
（20）“进口商”指任何在欧盟内设立的，将第三国进口的压力设备或组合件投放欧盟市场的，自然人或法人；

(21) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or assemblies available on the

market;
（21）“经销商”指任何在将压力设备或组合件进入市场供应链，且不是制造商或进口商的自然人或法人；

(22) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;
（22）‘经营者’指制造商、授权代表、进口商和经销商；

(23) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by pressure equipment or assemblies;
（23）“技术规范”指规定压力设备或组合件应满足的技术要求的文件；

(24) ‘harmonised standard’ means harmonised standard as defined in point (c) of Article 2(1) of Regulation (EU) No 1025/2012;
（24）“协调标准”指(EU) No 1025/2012 法规中第 2（1）条第 C 点定义的协调标准；

(25) ‘accreditation’ means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
（25）“认可”指(EC) No 765/2008 法规中第 2 条第 10 点定义的认可；

(26) ‘national accreditation body’ means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
（26）“国家认可机构”指(EC) No 765/2008 法规中第 2 条第 11 点定义的国家认可机构；

(27) ‘conformity assessment’ means the process demonstrating whether the essential safety requirements of this Directive relating to pressure equipment or assemblies have been fulfilled;
（27）“合格评定”指评定压力设备或组合件是否满足该指令基本安全要求的过程；

(28) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
（28）“合格评定机构”指执行合格评定活动，包括校准、测试、认证和检验的机构；

(29) ‘recall’ means any measure aimed at achieving the return of pressure equipment or assemblies that have already been made available to consumers or other users;
（29）“召回”指任何旨在满足退回已被消费者或其他用户使用的压力设备或组合件的措施；

(30) ‘withdrawal’ means any measure aimed at preventing pressure equipment or assemblies in the supply chain from being made available on the market;
（30）“撤回”指任何旨在防止供应链中的压力设备或组合件进入市场的措施；

(31) ‘CE marking’ means a marking by which the manufacturer indicates that the pressure equipment or assembly is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
（31）“CE 标识”是指制造商表明压力设备或组合件符合适用欧盟针对 CE 附缀协调法规要

求的标识；

(32) ‘Union harmonisation legislation’ means any Union legislation harmonizing the conditions for the marketing of products.
（32）“欧盟协调法规”指任何欧盟为协调产品市场环境制定的法规。

Article 3
第 3 条
Making available on the market and putting into service
投放市场和投入使用

1. Member States shall take all appropriate measures to ensure that pressure equipment and assemblies may be made available on the market and put into service only if they satisfy the requirements of this Directive when properly installed and maintained and used for the purposes for which they are intended.
1、各成员国应采取一切适当的措施，确保仅当压力设备和组合件在满足本指令的要求，正确安装、维护并依据预期范围使用时，才被投入市场和使用。

2. This Directive shall not affect Member States’ entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected during use of the pressure equipment or assembly in question provided that this does not mean modifications to such equipment or assembly in a way not specified in this Directive.
2、本指令不应影响成员国制订他们认为必需的、确保人员，尤其是工人在使用上述压力设备或组合件时得到保护的要求，只要这些要求不意味着用本指令未规定的方法对压力设备或组合件进行修改。

3. At trade fairs, exhibitions, demonstrations and other similar events, Member States shall not prevent the showing of pressure equipment or assemblies which do not comply with this Directive, provided that a visible sign clearly indicates that such pressure equipment or assemblies may not be made available on the market and/or put into service until they are brought into conformity. During demonstrations, appropriate safety measures shall be taken in accordance with any requirements laid down by the competent authority of the Member State concerned in order to ensure the safety of persons.
3、在交易会、展会和其他类似活动时，成员国不应阻止不符合本指令条款的压力设备或组合件的展出，只要清晰地指出该类压力设备在符合要求前可能无法再市场流通和/或使用。在展览期间，为确保人员安全，应按相关成员国权力机构制订的要求，采取适当的安全措施。

Article 4
第 4 条
Technical requirements
技术要求

1. The following pressure equipment shall satisfy the essential safety requirements set out in

Annex I:

1、下列压力设备应满足附录 I 所规定的基本安全要求：

(a) vessels, except those referred to in point (b), for:

（a）容器，除指在第（b）条所指的：

(i) gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

— for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 25 bar.L, or with a pressure PS greater than 200 bar (Annex II, table 1),

— for fluids in Group 2, with a volume greater than 1 L and a product of PS and V is greater than 50 bar.L, or with a pressure PS greater than 1 000 bar, and all portable extinguishers and bottles for breathing apparatus(Annex II, table 2);

(ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

— for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar.L, or with a pressure PS greater than 500 bar (Annex II, table 3),

— for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10 000 bar.L, or with a pressure PS greater than 1 000 bar (Annex II, table 4);

(a) 气体、液化气、压力溶解气体、蒸气及在最大允许温度下蒸气压超过标准大气压（1013 mbar）0.5 bar 的液体，受以下限制：

——用于组 1 的流体，其体积大于 1 L、PS 和 V 的乘积大于 25 barL 或压力 PS 大于 200 bar（附录 II，表 1）。

——用于组 2 流体，其体积大于 1 L、PS 和 V 的乘积大于 50 barL 或压力 PS 大于 1000 bar，以及所有手提灭火机和呼吸装置瓶（附录 II，表 2）。

(b) 在最大允许温度下，蒸气压不超过标准大气压（1013 mbar）0.5 bar 的液体，并受以下限制：

——用于组 1 的流体，其体积大于 1 L、PS 和 V 的乘积大于 200 barL 或压力 PS 大于 500 bar（附录 II，表 3）。

——用于组 2 流体，其压力 PS 大于 10 bar、PS 和 V 的乘积大于 10000 barL 或压力 PS 大于 1000 bar（附录 II，表 4）

(b) fired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or super- heated water at temperatures higher than 110 °C having a volume greater than 2 L, and all pressure cookers (Annex II, table 5);

（b）直接用火或其它方式加热，有过热危险的，用于产生温度超过 110 ℃蒸气或过热水，体积超过 2 L 的承压设备和所有的压力锅（附录 II，表 5）

(c) piping intended for:

（c）用于以下目的的管道：

(i) gases, liquefied gases, gases dissolved under pressure, vapours and those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal

atmospheric pressure (1 013 mbar) within the following limits:
— for fluids in Group 1 with a DN greater than 25 (Annex II, table 6),
— for fluids in Group 2 with a DN greater than 32 and a product of PS and DN greater than 1 000 bar (Annex II, table 7);
(a) 气体、液化气、受压溶解气体、蒸气及在最大允许温度下蒸气压超过标准大气压（1013 mbar）0.5 bar 的液体，受以下限制：
——用于组 1 流体，其 DN 大于 25（附录 II，表 6）。
——用于组 2 流体，其 DN 大于 32、PS 和 DN 的乘积大于 1000 bar（附录 II，表 7）。

(ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
— for fluids in Group 1 with a DN greater than 25 and a product of PS and DN greater than 2 000 bar (Annex II, table 8),
— for fluids in Group 2 with a PS greater than 10 bar, a DN greater than 200 and a product of PS and DN greater than 5 000 bar (Annex II, table 9).
(b) 在最大允许温度下蒸气压不超过标准大气压（1013 mbar）0.5 bar 的液体，受以下限制：
——用于组 1 流体，其 DN 大于 25、PS 和 DN 的乘积大于 2000 bar（附录 II，表 8）。
——用于组 2 流体，其 PS 大于 10 bar、DN 大于 200、PS 和 DN 的乘积大于 5000 bar（附录 II，表 9）。

(d) safety and pressure accessories intended for equipment covered by points (a), (b), and (c) including where such equipment is incorporated into an assembly.
（d）供（a）、（b）、（c）节涵盖的设备用的安全附件和压力附件、包括该设备并入到组合件的场合。

2. The following assemblies which include at least one item of pressure equipment covered by paragraph 1 shall satisfy the essential safety requirements set out in Annex I:
2、下列至少包括一款第一段所涵盖压力设备的组合件应满足附录 I 规定的基本安全要求：

(a) assemblies intended for generating steam or superheated water at a temperature higher than 110 °C comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating;
（a）用于产生温度高于 110° C 的蒸汽或过热水的组合件，至少包括一个用火或其他方式加热，表现出过热风险的压力设备组件；

(b) assemblies other than those referred to in point (a), if the manufacturer intends them to be made available on the market and put into service as assemblies.
（b）如果制造商打算投放市场，并作为组合件使用的，除（a）点所指的其他组合件。

By way of derogation from the first subparagraph, assemblies intended for generating warm water at temperatures not greater than 110 °C which are manually fed with solid fuels and have a PS.V greater than 50 bar.L shall comply with the essential safety requirements referred to in points 2.10, 2.11, 3.4, 5 (a) and 5 (d) of Annex I.
作为本节前段的降低要求，对于人工投放固体燃料，产生温度不超过 110℃热水且 PS*V 大

于 50 bar*L 的组合件，应符合附录 I 第 2.10,2.11,3.4,5(a)和 5(d)条的基本安全要求。

3. Pressure equipment and assemblies below or equal to the limits set out in points (a), (b) and (c) of paragraph 1 and in paragraph 2 respectively shall be designed and manufactured in accordance with the sound engineering practice of a Member State in order to ensure safe use. Pressure equipment and assemblies shall be accompanied by adequate instructions for use. Without prejudice to other applicable Union harmonisation legislation providing for its affixing, such equipment or assemblies shall not bear the CE marking referred to in Article 18.
为确保安全，低于或等于第(a), (b) 和 (c)节限制的压力设备和组合件必须按成员国优良工程要求设计和制造。压力设备和组合件应附带充分的说明书供使用。在不违背未其他适用的欧盟协调法规的情况下，该承压设备或组合件不应显示第 18 条的 CE 标识。

Article 5
第 5 条
Free movement
自由流通

1. Member States shall not, on grounds of the risks due to pressure, prohibit, restrict or impede the making available on the market or the putting into service under the conditions specified by the manufacturer of pressure equipment or assemblies which comply with this Directive.
1、 成员国不应以压力风险为理由，禁止、限制或阻止制造商制造符合本指令要求的压力设备或组合件投放市场，或在制造商规定的条件下投入使用。

Member States shall not, on grounds of the risks due to pressure, prohibit, restrict or impede the making available on the market or the putting into service of pressure equipment or assemblies which comply with Article 4(3).
成员国不应以压力风险为理由，禁止、限制或阻止符合第 4 条第三款第（3）点的压力设备或组合件投入市场或投入使用。

2. When a Member State has designated a user inspectorate in accordance with the requirements set out in Article 25, it may not, on grounds of the risks due to pressure, prohibit, restrict or impede the placing on the market or putting into service under the conditions provided for in Article 16, of pressure equipment or assemblies the conformity of which has been assessed by a user inspectorate designated by another Member State in accordance with the requirements set out in Article 25.
2、当成员国指定一个符合第 25 条要求的用户检验机构时，它不能在第 16 条规定的条件下，以压力风险为由，禁止、限制或阻碍已被另一成员国指定、符合第 25 条要求的用户检验机构评定的压力设备或组合件进入市场或投入使用。

3. Member States may require, to the extent that it is needed for safe and correct use of pressure equipment and assemblies, the information referred to in points 3.3 and 3.4 of Annex I to be provided in the official language(s) of the Union which may be determined by the Member State in which the equipment or assembly is made available on the market.
3、在某种程度上，成员国可以要求出于安全和正确使用压力设备和组合件的需要，由设备

或组合件投放市场的成员国指定，以欧盟官方语言提供附录 I 第 3.3 和 3.4 条提到的信息。

CHAPTER 2
第 2 章
OBLIGATIONS OF ECONOMIC OPERATORS
经营者义务
Article 6
第 6 条
Obligations of manufacturers
生产者义务

1. When placing their pressure equipment or assemblies referred to in Article 4(1) and (2) on the market or using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I.
1、当压力设备或组合件根据第 4 条第（1）和（2）款投入市场或自己使用时，制造商应确保他们已按附录 I 所规定的基本安全要求设计和制造。

When placing their pressure equipment or assemblies referred to in Article 4(3) on the market or using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the sound engineering practice of a Member State.
当将压力设备或组合件根据第 4 条第（3）款投入市场或自己使用时，制造商应确保他们已按成员国优良工程规范设计和制造。

2. For the pressure equipment or assemblies referred to in Article 4(1) and (2), manufacturers shall draw up the technical documentation referred to in Annex III and carry out the relevant conformity assessment procedure referred to in Article 14 or have it carried out. Where compliance of the pressure equipment or assemblies referred to in Article 4(1) and (2) with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph of this paragraph, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.
2、对于第 4 条第（1）和（2）款所指的压力设备或部件，制造商应制定附录 III 所指的技术文件，并根据第 14 条执行相关合格评定程序。当符合第 4 条（1）和（2）款所指的压力设备或组合件已经满足这一段第一小节提到的要求时，制造商应起草一份欧盟符合性声明并贴上 CE 标识。

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after pressure equipment or assemblies have been placed on the market.
3、压力设备或组合件投放市场后，制造商应保存技术文件和欧盟符合性声明 10 年。

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in design or characteristics of pressure equipment or assemblies and changes in the harmonised standards or in other technical specifications by reference to which conformity of pressure equipment or assemblies is declared shall be

adequately taken into account.
4、制造商应确保进行批量生产程序到位，以继续符合本指令要求。应充分考虑压力设备或组合件的设计或特征变更，压力设备或组合件合格参考的协调标准或其他技术规范的变更。

When deemed appropriate with regard to the risks presented by pressure equipment or assemblies, manufacturers shall, to protect the health and safety of consumers and other users, carry out sample testing of pressure equipment or assemblies made available on the market, investigate, and, if necessary, keep a register of complaints of non-conforming pressure equipment and assemblies and recalls of such equipment, and shall keep distributors informed of any such monitoring.
当被合理认为是压力设备或组合件造成的风险时，为保护消费者和其他用户的健康和安全，制造商应对市场上现有的压力设备或组合件进行样品测试并调查。如有必要，对被投诉的不合格压力设备和组合件进行登记并召回，并应通知经销商任何类似的监管。

5. Manufacturers shall ensure that their pressure equipment or assemblies bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the equipment or assembly does not allow it, that the required information is provided on the packaging or in a document accompanying the equipment.
5、制造商应确保他们的压力设备或组合件印有型号、批号或序列号或其他可供识别的元素，或者，当设备或组合件的大小或性质不允许时，应在包装或随设备的文件中提供要求的信息。

6. Manufacturers shall indicate on the pressure equipment or assembly their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on the packaging or in a document accompanying the equipment or assembly. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by consumers, other users and market surveillance authorities.
6、制造商应在压力设备或组合件上标明其名称、注册品牌或注册商标，以及他们的联系地址。若不可以，应在包装或随设备的文件中提供。地址应指向制造商单一的、可以联系的位置。详细联系方式应使用消费者、其他用户和市场监管机构容易理解的语言描述。

7. Manufacturers shall ensure that the pressure equipment or assemblies referred to in Article 4(1) and (2) is accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable and intelligible.
7、制造商应确保第 4 条第（1）和（2）款所指的压力设备或组合件附有根据附录 I 第 3.3 和 3.4 条确定的说明和安全信息，并由一种相关成员国确定的、可被消费者和其他用户容易理解的语言编写。该说明和安全信息必须清晰、可理解且易懂的。

Manufacturers shall ensure that the pressure equipment or assemblies referred to in Article 4(3) are accompanied by instructions and safety information in accordance with Article 4(3), in a language which can be easily understood by consumers and other users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable

and intelligible.
制造商应确保第 4 条第（3）款所指的压力设备或组合件附有依据第 4 条第（3）款确定的说明和安全信息，并由一种相关成员国确定的、可被消费者和其他用户容易理解的语言编写。该说明和安全信息必须清晰、可理解且易懂的。

8. Manufacturers who consider or have reason to believe that pressure equipment or assemblies which they have placed on the market are not in conformity with this Directive shall immediately take the corrective measures necessary to bring that pressure equipment or those assemblies into conformity, to withdraw it or recall it, if appropriate. Furthermore, where pressure equipment or assemblies present a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made that pressure equipment or those assemblies available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8、当制造商认为或有理由相信他们投放市场的压力设备或组合件不符合本指令时，应立即采取必要的纠正措施，使该压力设备或组合件满足要求。如有必要，撤回或召回产品。此外，当压力设备或组合件显示出风险时，制造商应立即通知批准该压力设备或组合件进入市场、造成这一影响的成员国国家主管机构，提供风险细节，特别是不符合项和任何已进行的纠正措施。

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly with this Directive, in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the pressure equipment or assembly which they have placed on the market.
9、制造商应进一步满足来自国家主管机构的合理要求，以一种容易被主管部门理解的语言，提供所有能表明压力设备或组合件符合本指令的信息和文档。这些信息和文档可以以纸质或电子的形式提供。制造商应按主管部门要求进行合作，采取一切行动消除他们投放市场的压力设备或组合件带来的风险。

Article 7
第 7 条
Authorised representatives
授权代表

1. A manufacturer may, by a written mandate, appoint an authorised representative. The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.
1、制造商可以通过书面授权指定授权代表。第 6 条第（1）款规定的义务和第 6 条第（2）款制定技术文件的义务不作为被授权代表义务的一部分。

2. An authorised representative shall perform the tasks specified in the mandate received from

the manufacturer. The mandate shall allow the authorised representative to do at least the following:
2、授权代表应执行制造商提供授权书中的指定任务。授权书应至少允许授权代表执行以下行为：

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the pressure equipment or assembly has been placed on the market;
（a）在压力设备或组合件投放市场后，在国家市场监管机构处理下，保管欧盟符合性声明和技术文件 10 年；

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly;
（b）当国家主管机构提出合理要求时，向该机构提供所有能表明压力设备或组合件合格的信息和文档；

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by the pressure equipment or assembly covered by the authorised representative's mandate.
（c）在有关国家机构的要求下，与他们合作，采取一切行动消除授权代表文件上涵盖的压力设备或组合件所带来的风险。

Article 8
第 8 条
Obligations of importers
进口商的义务

1. Importers shall place only compliant pressure equipment or assemblies on the market.
1、进口商应仅将合规的压力设备或组合件投放进市场。

2. Before placing on the market the pressure equipment or assemblies referred to in Article 4(1) and (2), importers shall ensure that the appropriate conformity assessment procedure in accordance with Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that pressure equipment or assemblies bear the CE marking and are accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).
2、在将第 4 条第（1）和（2）款所指的压力设备或组合件投放市场前，进口商应确保制造商已按照第 14 条的规定，进行合适的合格评定程序。他们应确保制造商已经制定了技术文件，该压力设备或组合件标上了 CE 标识，附有附录 I 第 3.3 和 3.4 条要求的说明和安全信息，并且制造商已满足第 6 条第（5）和（6）款的要求。

Before placing on the market the pressure equipment or assemblies referred to in Article 4(3),

importers shall ensure that the manufacturer has drawn up the technical documentation and that pressure equipment or assemblies are accompanied by adequate instructions for use and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).
投放第 4 条第（3）款所指的压力设备或组合件进入市场前，进口商应确保制造商已经制定了技术文件，并且压力设备或组合件附有足够的使用说明，并且制造商已满足第 6 条第（5）和（6）款的要求。

Where an importer considers or has reason to believe that the pressure equipment or assembly is not in conformity with the essential safety requirements set out in Annex I, he shall not place the pressure equipment or assembly on the market until it has been brought into conformity. Furthermore, where the pressure equipment or assembly presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.
当进口商认为或有理由相信压力设备或组合件不符合附录 I 基本安全要求时，在该压力设备或组合件满足要求前，不应将该压力设备或组合件投放市场。此外，在压力设备或组合件表现出风险时，进口商应立即将该影响通知给制造商和市场监管机构。

3. Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the pressure equipment or assembly, or, where that is not possible, on its packaging or in a document accompanying the equipment or assembly. The contact details shall be in a language easily understood by consumers, other users and market surveillance authorities.
3、进口商应在压力设备或组合件上标明他们的名称、注册品牌或注册商标和可供联系邮政地址。或当不可以时，在其包装、或随设备或组合件的文件中标明。详细的联系方式应以消费者、其他用户和市场监管机构容易理解的语言写出。

4. Importers shall ensure that pressure equipment or assemblies referred to in Article 4(1) and (2) are accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users, as determined by the Member State concerned.
4、进口商应确保在第 4 条第（1）和（2）款所指的压力设备或组合件附有符合附录 I 第 3.3 和 3.4 条要求的说明和安全信息，按相关成员国要求，以一种消费者和其他用户容易理解的语言写出。

Importers shall ensure that the pressure equipment or assembly referred to in Article 4(3) is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users, as determined by the Member State concerned.
进口商应确保在第 4 条第（3）款所指的压力设备或组合件附有说明及安全信息，按相关成员国要求，以一种消费者和其他用户容易理解的语言写出。

5. Importers shall ensure that, while pressure equipment or assemblies referred to in Article 4(1) and (2) are under their responsibility, storage or transport conditions do not jeopardise their compliance with the essential safety requirements set out in Annex I.
5、当进口商负责第 4 条第（1）和（2）款所指的压力设备或组合件时，进口商应保证储存或运输条件不影响他们满足载于附录 I 的基本安全要求。

6. When deemed appropriate with regard to the risks presented by pressure equipment or assemblies, importers shall, to protect the health and safety of consumers and other users, carry out sample testing of pressure equipment and assemblies made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming pressure equipment or assemblies and recalls of such equipment, and shall keep distributors informed of any such monitoring.
6、当被合理认为是压力设备或组合件所造成的风险时，为保护消费者和其他用户的健康和安全，进口商应对市场上现有的压力设备或组合件进行样品测试并调查。如果有必要，对被投诉的不合格压力设备和组合件进行登记并召回，并应通知经销商任何类似的监管。

7. Importers who consider or have reason to believe that pressure equipment or assemblies which they have placed on the market are not in conformity with this Directive shall immediately take the corrective measures necessary to bring that pressure equipment or assembly into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the pressure equipment or assembly presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the pressure equipment or assembly available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
7、当进口商认为或有理由相信他们投放市场的压力设备或组合件不符合本指令时，应立即采取必要的纠正措施，使该压力设备或组合件满足要求。如有必要，撤回或召回产品。此外，在压力设备或组合件表现出风险时，进口商应立即通知允许这些压力设备或组合件进入市场，造成这一影响的成员国国家主管机构，提供风险细节，特别是不符合项和任何已进行的纠正措施。

8. Importers shall, for 10 years after the pressure equipment or assembly has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.
8、在压力设备或组合件投放市场后，进口商应在国家市场监管机构处理下，保存欧盟符合性声明和技术文件备份 10 年。并确保如有需求，可供主管部门使用该技术文件。

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of pressure equipment or an assembly in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pressure equipment or an assembly which they have placed on the market.
9、进口商应进一步满足来自国家主管机构的合理要求，以一种容易被主管部门理解的语言，提供所有能表明压力设备或组合件符合本指令的信息和文件。这些信息和文件可以以纸质或电子的形式提供。进口商应按主管部门要求进行合作，采取一切行动消除他们投放在市场上的压力设备或组合件所带来的风险。

Article 9

第 9 条
Obligations of distributors
经销商义务

1. When making pressure equipment or assemblies available on the market distributors shall act with due care in relation to the requirements of this Directive.
1、当压力设备或组合件在市场上流通时，经销商应按本指令要求的行为准则行动。

2. Before making the pressure equipment or assemblies referred to in Article 4(1) and (2) available on the market distributors shall verify that the pressure equipment or assembly bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users in the Member State in which the pressure equipment or assembly is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.
2、在将第 4 条第（1）和（2）款所指的压力设备或组合件投放市场前，经销商应确保该压力设备或组合件印有 CE 标识，附有附录 I 第 3.3 和 3.4 条要求的说明和安全信息，并以消费者和压力设备或组合件进入的成员国市场的其他用户容易理解的语言写出。并且制造商和进口商已遵守第 6 条（5）和（6）款和第 8 条第（3）款的要求。

Where a distributor considers or has reason to believe that pressure equipment or assemblies are not in conformity with the essential safety requirements set out in Annex I, he shall not make the pressure equipment or assembly available on the market until it has been brought into conformity. Furthermore, where the pressure equipment or assembly presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.
当经销商认为或有理由相信他们投放市场的压力设备或组合件不符合附录 I 的基本安全要求时，在压力设备或组合件符合要求前，应阻止产品在市场上流通。此外，在压力设备或组合件表现出风险时，经销商应立即通知生产商、进口商，以及市场监管机构该影响。

Before making the pressure equipment or assembly referred to in Article 4(3) available on the market, distributors shall verify that that pressure equipment or assembly is accompanied by adequate instructions for use, in a language which can be easily understood by consumers and other users in the Member State in which that pressure equipment or assembly is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.
投放第 4 条第（3）款所指的压力设备或组合件进入市场前，进口商应确保制造商已经制定了技术文件，并且压力设备或组合件附有足够的使用说明，以消费者和压力设备或组合件进入的成员国市场的其他用户容易理解的语言写出。并且制造商和进口商已遵守第 6 条第（5）和（6）款和第 8 条第（3）款的要求。

3. Distributors shall ensure that, while the pressure equipment or assemblies referred to in Article 4(1) and (2) are under their responsibility, storage or transport conditions do not jeopardise their compliance with the essential safety requirements set out in Annex I.

3、当对第 4 条第（1）和（2）款所指的压力设备或组合件负责时，经销商应保证储存或运输条件不影响他们满足载于附录 I 的基本安全要求。

4. Distributors who consider or have reason to believe that pressure equipment or assemblies which they have made available on the market are not in conformity with this Directive shall make sure that the corrective measures necessary to bring that equipment or assembly into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the pressure equipment or assembly presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the equipment or assembly available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
4、当经销商认为或有理由相信他们投放市场的压力设备或组合件不符合本指令时，应立即采取必要的纠正措施，使该压力设备或组合件满足要求。如有必要，撤回或召回产品。此外，当压力设备或组合件表现出风险时，经销商应立即通知允许这些压力设备或组合件进入市场，造成这一影响的成员国国家主管机构，提供风险细节，特别是不符合项和任何已进行的纠正措施。

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of pressure equipment or assemblies. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the pressure equipment or assemblies which they have made available on the market.
5、经销商应进一步满足来自国家主管机构的合理要求，提供所有能表明压力设备或组合件符合本指令的信息和文件。这些信息和文件可以以纸质或电子的形式提供。经销商应按主管部门要求进行合作，采取一切行动消除他们投放市场的压力设备或组合件所带来的风险。

Article 10
第 10 条
Cases in which obligations of manufacturers apply to importers and distributors
制造商义务适用于进口商和经销商的情形

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places pressure equipment or an assembly on the market under his name or trademark or modifies pressure equipment or an assembly already placed on the market in such a way that compliance with the requirements of this Directive may be affected.
当进口商或经销商以自己的名义或商标将压力设备或组合件投放市场，或改装已在市场上的压力设备或组合件，可能会影响（设备）符合本指令要求时，他应按本指令的目的，被视为制造商，并应遵守第 6 条制造商义务。

Article 11
第 11 条
Identification of economic operators

经营者的定义

Economic operators shall, on request, identify the following to the market surveillance authorities:
经营者应按要求，向市场监管机构确认以下信息：

(a) any economic operator who has supplied them with pressure equipment or an assembly;
（a）任何为他们提供压力设备或组合件的经营者；
(b) any economic operator to whom they have supplied pressure equipment or an assembly.
（b）任何他们供应压力设备或组合件的经营者。

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the pressure equipment or assembly and for 10 years after they have supplied the pressure equipment or assembly.
经营者应当在获得压力设备或组合件后的 10 年内，或是他们提供了压力设备或组合件后的 10 年内，提供第一段所要的信息。

CHAPTER 3
第 3 章
CONFORMITY AND CLASSIFICATION OF PRESSURE EQUIPMENT AND ASSEMBLIES
压力设备和组合件的整理和分类
Article 12
第 12 条
Presumption of conformity
推定符合

1. Pressure equipment or assemblies referred to in Article 4(1) and (2) which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential safety requirements covered by those standards or parts thereof, referred to in Annex I.
1、第 4 条第（1）和（2）款所指的、已符合发表在欧盟官方杂志上的协调标准或其部分的压力设备或组合件，根据附录 I，推定符合这些标准或其部分所涉及的基本安全要求，

2. The materials used for the manufacture of pressure equipment or assemblies which are in conformity with European approvals for materials, the references of which have been published in the Official Journal of the European Union in accordance with Article 15(4), shall be presumed to be in conformity with the applicable essential safety requirements set out in Annex I.
2、用于制造压力设备或组合件，符合欧洲材料批准的材料，及根据第 15 条第 4 款已在欧盟官方杂志上刊载的参考材料，应推定符合满足附录 I 的基本安全要求。

Article 13
第 13 条
Classification of pressure equipment
压力设备分类

1. Pressure equipment referred to in Article 4(1) shall be classified by category in accordance with Annex II, according to an ascending level of hazard.
1、第 4 条第（1）款所指的压力设备，应按附录 II 的规定，按风险等级提高进行分类：

For the purposes of such classification fluids shall be divided into the following two groups:
对于这样的分类，流体应分为以下两组：

(a) group 1 consisting of substances and mixtures, as defined in points (7) and (8) of Article 2 of Regulation (EC) No 1272/2008, that are classified as hazardous in accordance with the following physical or health hazard classes laid down in Parts 2 and 3 of Annex I to that Regulation:
（a）组 1 由物质和混合物组成，如在(EC) No 1272/2008 法规第 2 条第（7）和第（8）点所定义的，按照附录 I 第 2 和第 3 部分的规定，下列物理或健康危害类别被列为危险品：

(i) unstable explosives or explosives of Divisions 1.1, 1.2, 1.3, 1.4 and 1.5;
（i）不稳定爆炸物或分类为 1.1、1.5、1.3、1.4 和 1.2 的爆炸物；
(ii) flammable gases, category 1 and 2;
（ii）可燃气体，类别 1 和 2；
(iii) oxidising gases, category 1;
（iii）氧化气体，类别 1；
(iv) flammable liquids, category 1 and 2;
（iv）易燃液体，类别 1 和 2；
(v) flammable liquids, category 3 where the maximum allowable temperature is above the flashpoint;
（v）易燃液体，在最大允许温度高于闪点温度的类别 3；
(vi) flammable solids, category 1 and 2;
（vi）易燃固体，类别 1 和 2；
(vii) self-reactive substances and mixtures, type A to F;
（vii）自反应物质和混合物，种类 A 至 F；
(viii) pyrophoric liquids, category 1;
（viii）自燃液体，类别 1；
(ix) pyrophoric solids, category 1;
（ix）自燃固体，类别 1；
(x) substances and mixtures which in contact with water emit flammable gases, category 1, 2 and 3;
（x）与水接触可释放出可燃气体的物质和混合物，类别 1、2 和 3；
(xi) oxidising liquids, category 1, 2 and 3;
（xi）氧化性液体，类别 1，2 和 3；
(xii) oxidising solids, category 1, 2 and 3;
（xii）氧化性固体，类别 1，2 和 3；
(xiii) organic peroxides types A to F;
（xiii）有机过氧化物，种类 A 到 F；
(xiv) acute oral toxicity, category 1 and 2;
（xiv）急性口服毒剂，类别 1 和 2；

(xv) acute dermal toxicity, category 1 and 2;
（xv）急性皮肤性毒剂，类别 1 和 2；
(xvi) acute inhalation toxicity, category 1, 2 and 3;
（xvi）急性吸入性毒剂，类别 1，2 和 3；
(xvii) specific target organ toxicity – single exposure, category 1.
（xvii）特殊针对器官的毒剂－单次接触，类别 1。

Group 1 comprises also substances and mixtures contained in pressure equipment with a maximum allowable temperature TS which exceeds the flashpoint of the fluid;
组 1 还包括压力设备中含有最大允许温度超过液体闪点的物质和混合物；

(b) group 2 consisting of substances and mixtures not referred to in point (a).
（b）组 2 由（a）条未提及的物质和混合物组成。

2. Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers. Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.
2、当容器由几个腔体组成时，应按各腔体中最高类别进行分类。如果腔体内含有多种流体，应按最高类别的流体进行分类。

Article 14
第 14 条
Conformity assessment procedures
合格评定程序

1. The conformity assessment procedures to be applied to an item of pressure equipment shall be determined by the category, as set out in Article 13, in which the equipment is classified.
1、适用于压力设备部件的合格评定程序类别应由第 13 条所列设备分类决定。

2. The conformity assessment procedures to be applied for the various categories are the following:
2、适用于各类别的合格评定程序如下：

(a) category I:
— Module A
（a）类别 I：
模式 A

(b) category II:
— Module A2
— Module D1
— Module E1
（b）类别 II：
——模式 A2

——模式 D1
——模式 E1

(c) category III:
— Modules B (design type) + D
— Modules B (design type) + F
— Modules B (production type) + E
— Modules B (production type) + C2
— Module H
（c）类别 III：
——模式 B（design type）+ D
——模式 B（design type）+ F
——模式 B（production type）
——模式 B（production type）+ C2
——模式 H

(d) category IV:
（d）类别 IV：
— Modules B (production type) + D
— Modules B (production type) + F
— Module G
— Module H1
——模式 B（production type）+ D
——模式 B（production type）+ F
——模式 G
——模式 h

The conformity assessment procedures are set out in Annex III.
合格评定程序载于附录 III。

3. Pressure equipment shall be subject to one of the conformity assessment procedures which may be chosen by the manufacturer among those laid down for the category in which it is classified. The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.
3、制造商可根据承压设备类别，选择该类所列的合格评定程序对承压设备进行合格评定。如可行，制造商也可选择更高类别的合格评定程序。

4. In the framework of quality assurance procedures for pressure equipment in categories III and IV referred to in point (i) of point (a) of Article 4(1), first indent of point (ii) of point (a) of Article 4(1) and point (b) of Article 4(1), the notified body shall, when performing unexpected visits, take a sample of equipment from the manufacturing or storage premises in order to perform, or have performed, the final assessment as referred to in Annex I, point 3.2. To this end, the manufacturer shall inform the notified body of the intended schedule of production. The notified body shall carry out at least two visits during the first year of manufacturing. The frequency of

subsequent visits shall be determined by the notified body on the basis of the criteria set out in point 4.4 of modules D, E and H and point 5.4 of module H1.
4、对于第 4 条第（1）款第（a）节的第（i）点，第 4 条第（1）款第（a）节的第（ii）点和第 4 条第（1）款第（b）节的第 III、IV 类设备的质量保证程序框架，公告机构应在进行不定期检查时，抽取正在制造或储存的设备样品，按附录 I 第 3.2 节进行最终评审。因此，制造商应告知公告机构其预定的生产计划。公告机构在制造第一年至少应进行两次这样的拜访。公告机构应根据模式 D、E 和 H 的第 4.4 条和模式 H1 的第 5.4 条准则，决定以后拜访的频率。

5. In the case of one-off production of vessels and pressure equipment in category III referred to in point (b) of Article 4(1) under the module H procedure, the notified body shall perform or have performed the final assessment, as referred to in point 3.2 of Annex I, for each unit. To this end, the manufacturer shall communicate the intended schedule of production to the notified body.
5、对于按模式 H、第 4 条第（1）款（b）节所述的第 III 类一次性生产的容器和设备，公告机构应按附录 I 第 3.2 节对每一件进行最终评审。为此，制造商应通知公告机构其预定生产计划。

6. Assemblies referred to in Article 4(2) shall be subject to a global conformity assessment procedure comprising the following assessments:
6、第 4 条第（2）款提到的组合件应属于综合合格评定程序，包含以下评定：

(a) the assessment of each item of pressure equipment making up the assembly and referred to in Article 4(1) which has not been previously subjected to a conformity assessment procedure and to a separate CE marking; the assessment procedure shall be determined by the category of each item of equipment;
（a）第 4 条第（1）款所指的之前未经合格评定程序、也没有单独带有 CE 标记的每件对组成组合件的承压设备进行评定；评定程序取决于单独设备的类别

(b) the assessment of the integration of the various components of the assembly as referred to in points 2.3, 2.8 and 2.9 of Annex I which shall be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories;
（b）对附录 I 第 2.3、2.8 和 2.9 节组成组合件的不同元件进行整体评定，应由相关承压设备的最高类别确定，而不是按安全附件的要求。

(c) the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in points 2.10 and 3.2.3 of Annex I shall be conducted in the light of the highest category applicable to the items of equipment to be protected.
（c）对附录 I 第 2.10、3.2.3 节所述防止超出允许操作极限的组合件的评定，应按适合受保护承压设备的最高类别进行。

7. By way of derogation from paragraphs 1 and 2 of this Article, the competent authorities may, where justified, allow the making available on the market and putting into service in the territory of the Member State concerned of individual pressure equipment items and assemblies referred to in Article 2, in respect of which the procedures referred to in paragraphs 1 and 2 of this Article

have not been applied and the use of which is in the interests of experimentation.
7、对于本条第 1 和第 2 段降低要求的情况，能力机构在合理时，考虑到未采用本条第 1 段和 2 段的程序并作为实验目的使用，可允许第 2 条提到的个别压力设备和组合件在该成员国范围内投放市场和投入服务。

8. The records and correspondence relating to conformity assessment procedures shall be drafted in an official language of the Member State where the body responsible for carrying out these conformity assessment procedures is established, or in a language accepted by that body.
8、合格评定的记录和函件应使用由负责进行合格评定程序的机构成立的成员国官方语言、或该机构认可的语言拟定。

Article 15
第 15 条
European approval for materials
欧洲材料批准

1. European approval for materials shall be issued at the request of one or more manufacturers of materials or equipment, by one of the notified bodies referred to in Article 20 specifically designated for that task. The notified body shall determine and perform, or arrange for the performance of, the appropriate inspections and tests to certify the conformity of the types of material with the corresponding requirements of this Directive. In the case of materials recognised as being safe to use before 29 November 1999, the notified body shall take account of the existing data when certifying such conformity.
1、欧洲材料批准应在材料或设备的一个或多个制造商申请后，由专门执行该职责的第 20 条所指的公告机构发布。公告机构应确定并实施或安排实施核实的检测和检验，以验证该类型材料符合本指令相应要求；如果材料在 1999 年 11 月 29 日之前被确认为可以安全使用，则公告机构在验证符合时应考虑现有数据。

2. Before issuing a European approval for materials, the notified body shall notify the Member States and the Commission by sending them the appropriate information. Within three months, a Member State or the Commission may provide comments giving its reasons. The notified body may issue the European approval for materials taking into account the comments submitted.
2、在发布欧洲材料批准之前，公告机构（Notified Body，如阿拜维 APAVE）应将有关信息通知成员国和委员会。成员国或委员会可在三个月之内给出评论并说明原因。公告机构（Notified Body，如阿拜维 APAVE）在申请欧洲材料批准时应考虑提交的评论。

3. A copy of the European approval for materials shall be sent to the Member States, the notified bodies and the Commission.
3、欧洲材料批准的副本应发送至各成员国、公告机构（Notified Body，如阿拜维 APAVE）和委员会。

4. When the European approval for materials satisfies the requirements which it covers and which are set out in Annex I, the Commission shall publish the references of that approval. The Commission shall keep up to date a list of such approvals in the Official Journal of the European

Union.
4、当欧洲材料批准满足它涵盖的要求及附录 I 要求时，委员会应发布批准参考。委员应在应及时在欧共体官方刊物更新该批准清单。

5. The notified body which issued the European approval for materials shall withdraw that approval if it finds that it should not have been issued or if the type of materials is covered by a harmonised standard. It shall immediately inform the other Member States, the notified bodies and the Commission of any withdrawal of an approval.
5、若公告机构（Notified Body，如阿拜维 APAVE）发现已发布的欧洲材料批准不应被发布，或该类型材料已被协调标准所覆盖，它应撤回该批准。它应立即通知其他成员国、公告机构（Notified Body，如阿拜维 APAVE）和委员会任何批准的撤回。

6. When a Member State or the Commission considers that a European approval for materials whose references have been published in the Official Journal of the European Union, does not entirely satisfy the essential safety requirements which it covers and which are set out in Annex I, the Commission shall decide by means of implementing acts whether to withdraw the references of that European approval for materials from the Official Journal of the European Union. The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).
6、当成员国或委员会认为其参考的已发布在欧盟官方杂志上的欧洲材料批准并不能完全满足它涵盖的或附录 I 的基本安全要求，委员会应决定是否通过实施法令，撤回欧盟官方杂志上的欧洲材料批准参考。本段第一小段所指的实施法令应依照第 44 条第（3）款所指的检查程序执行

Article 16
第 16 条
User inspectorates
用户检验机构

1. By way of derogation from the provisions relating to the tasks carried out by the notified bodies, Member States may authorise on their territory the placing on the market and the putting into service by users, of pressure equipment or assemblies of which conformity with the essential safety requirements has been assessed by a user inspectorate designated in accordance with paragraph 7.
1、通过减少公告机构执行任务的办法，成员国可以授权根据第 7 段设立的用户检验机构进行评定的，符合基本安全要求的压力设备或组合件在其境内投放市场和投入使用。

2. Pressure equipment and assemblies the conformity of which has been assessed by a user inspectorate shall not bear the CE marking.
2、由用户检验机构进行合格评定的承压设备或组合件不得印制 CE 标识。

3. The pressure equipment or assemblies referred to in paragraph 1 may be used only in establishments operated by the group of which the inspectorate is part. The group shall apply a common safety policy as regards the technical specifications for the design, manufacture,

inspection, maintenance and use of pressure equipment and assemblies.
3、第 1 段所指的压力设备或组合件仅可在用户检验机构只是该集团的一部分的内部使用。集团应对压力设备和组合件的设计、制造、检验、维护和使用的技术文件制订相同的安全政策。

4. The user inspectorates shall act exclusively for the group of which they are part.
4、作为集团的一部分，用户检验机构应专门为集团行动。

5. The conformity assessment procedures applicable by user inspectorates shall be modules A2, C2, F and G, set out in Annex III.
5、用户检验机构适用的合格评定程序应为附录 III 设定的模式 A2、C2，F 和 G。

6. Member States shall notify the other Member States and the Commission which user inspectorates they have authorised, the tasks for which they have been designated and, for each inspectorate, a list of the establishments satisfying the provisions of paragraph 3.
6、成员国应公告其他成员国和委员会其授权的用户检验机构、所授权的任务，并对每个检验机构建立满足第 3 段条款的清单。

7. In designating the user inspectorates, the Member States shall apply the requirements set out in Article 25 and ensure that the group of which the inspectorate is part applies the criteria referred to in the second sentence of paragraph 3 of this Article.
7、在授权用户检验机构时，成员国应执行第 25 条的要求，并确保用户检验机构只是其中一部分的集团执行第 3 段第 2 句的准则。

Article 17
第 17 条
EU declaration of conformity
欧盟符合性声明

1. The EU declaration of conformity shall state that the fulfilment of essential safety requirements set out in Annex I has been demonstrated.
1、欧盟符合性声明应表明附录 I 所规定的基本安全要求已被满足。

2. The EU declaration of conformity shall have the model structure set out in Annex IV and shall contain the elements specified in the relevant conformity assessment procedures set out in Annex III and shall be continuously updated. It shall be translated into the language or languages required by the Member State in whose market the pressure equipment or assembly is placed or made available on the market.
2、欧盟符合性声明应具有附录 IV 所列的结构模板，并应包含附录 III 规定的相关合格评定程序元素，并应不断更新。它应被翻译成压力设备或组合件被投放市场，或在市场流通的成员国所要求的一种或多种语言。

3. Where pressure equipment or an assembly is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect

of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.
3、当压力设备或组合件属于超过一个需要欧盟符合性声明的欧盟法规， 应针对所有欧盟法规制定单一的欧盟符合性声明。该声明应包含相关欧盟法规的确定，包括其参考的发布文献。

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the pressure equipment or assembly with the requirements laid down in this Directive.
4、通过制定欧盟符合性声明，应认为制造商对压力设备或组合件符合本指令要求负责。

Article 18
第 18 条
General principles of the CE marking
CE 标识的一般原则

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
CE 标识应服从(EC) No 765/2008 法规第 30 条的一般性原则。

Article 19
第 19 条
Rules and conditions for affixing the CE marking
附缀 CE 标识的规则和条件

1. The CE marking shall be affixed visibly, legibly and indelibly to any of the following:
(a) each item of pressure equipment referred to in Article 4(1) or its dataplate;
(b) each assembly referred to in Article 4(2) or its dataplate.
1、下列任何产品的 CE 标识必须是明显的、清晰的且不可磨灭的：
（a）每个第 4 条第（1）款所指的压力设备或其铭牌；
（b）每个第 4 条第（2）款所指的组合件或其铭牌。

Where the affixing of the CE marking is not possible or not warranted on account of the nature of the equipment or assembly, it shall be affixed to the packaging and to the accompanying documents.
当考虑到设备或组合件本身特性，无法粘贴 CE 标志或不必要时，应将其固定在包装和附带的文件上。

The item or assembly referred to in points (a) and (b) of the first subparagraph shall be complete or shall be in a state permitting final assessment as described in point 3.2 of Annex I.
第一小段第（a）和（b）点所指的设备或组合件应保持完整，或处于附录 I 第 3.2 条所述的允许最终评定的状态。

2. It is not necessary for the CE marking to be affixed to each individual item of pressure equipment making up an assembly. Individual items of pressure equipment already bearing the

CE marking when incorporated into the assembly shall continue to bear that marking.
2、没有必要为组成组合件的每个单独压力设备组粘贴 CE 标识。当已带有 CE 标识的单独压力设备并入组合件时，应继续印制该标识。

3. The CE marking shall be affixed before the item of pressure equipment or the assembly is placed on the market.
3、在压力设备或组合件投入市场前，必须附上 CE 标识。

4. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.
4、CE 标识应与参与生产控制阶段的公告机构（Notified Body，如阿拜维 APAVE）编号放在一起。由制造商或其授权代表将公告机构（Notified Body，如阿拜维 APAVE）编码附在设备本身或说明书内。

5. The CE marking and, where applicable, the identification number referred to in paragraph 4 may be followed by any other mark indicating a special risk or use.
5、CE 标识和在第 4 段中提到的编号（如适用）之后可附带其他特殊风险或使用的标识。

6. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.
6、成员国应建立现有机制，确保正确使用 CE 标识，并应在未能正确使用该标记的情况采取适当的行动。

CHAPTER 4
第 4 章
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES
合格评定机构公告
Article 20
第 20 条
Notification
公告

Member States shall notify the Commission and the other Member States of the notified bodies and the user inspectorates authorised to carry out conformity assessment tasks in accordance with Article 14, Article 15 or Article 16 and of the third-party organisations they have recognised, for the purposes of the tasks referred to in points 3.1.2 and 3.1.3 of Annex I.
各成员国应通知委员会和其他成员国，根据第 14 条、第 15 条或第 16 条的规定，被授权执行合格评定任务的公告机构（Notified Body，如阿拜维 APAVE）和用户检验机构和他们认可的、执行附录 I 第 3.1.2 和 3.1.3 条所指任务的第三方组织。

Article 21

第 21 条
Notifying authorities
公告主管机构

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, recognised third-party organisations and user inspectorates, including compliance with Article 27.
1、成员国应指定一个公告主管机构，负责建立、以及执行评定和公告合格评定机构的必要程序，并监督公告机构（Notified Body，如阿拜维 APAVE）、认可的第三方组织和用户检验机构，及其第 27 条规定的机构。

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
2、成员国可以将第 1 段所指的评定和监督由一个按照(EC) No 765/2008 法规定义并符合该法规的国家认可机构执行。

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 22. In addition it shall have arrangements to cover liabilities arising out of its activities.
3、当公告主管机构将第 1 段提到的评定、公告或监督任务授权或委托到一个非政府机构时，该机构应是一个法律实体，并应对照符合第 22 条规定的要求。此外，它应签订协议，以含盖其义务。

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.
4、公告主管机构对第 3 段所指机构的任务承担所有责任。

Article 22
第 22 条
Requirements relating to notifying authorities
有关公告主管机构的要求

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
1、公告主管机构应以不会与合格评定机构产生利益冲突的方式建立。

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
2、公告主管机构的组织和运作应保证其活动的客观性和公正性。

3. A notifying authority shall be organised in such a way that each decision relating to notification

of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
3、公告主管机构应以这样一种方式组织，由来自不是那些被评定机构的称职人员，决定每一个与合格评定机构公告有关的事项。

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
4、公告主管机构不得给予或提供合格评定机构进行的任何活动，或基于商业或竞争的顾问服务。

5. A notifying authority shall safeguard the confidentiality of the information it obtains.
5、公告主管机构应保证其获得信息的保密性。

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.
6、公告主管机构应有足够数量的称职人员，以保证其任务被妥善处理。

Article 23
第 23 条
Information obligation on notifying authorities
公告主管机构的信息义务

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, recognised third-party organisations and user inspectorates, and of any changes thereto. The Commission shall make that information publicly available.

成员国应通知委员会它们评定和公告合格评定机构，并监督公告机构（Notified Body，如阿拜维 APAVE）、认可的第三方组织和用户检验机构的程序，以及其任何变更。委员会应公开提供该信息。

Article 24
第 24 条
Requirements relating to notified bodies and recognised third-party organisations
有关公告机构和认可第三方组织的要求

1. For the purposes of notification, a notified body or recognised third party organisation shall meet the requirements laid down in paragraphs 2 to 11.
1、公告的目的在于公告机构或认可第三方组织应符合第 2 至 11 段的要求。

2. A conformity assessment body shall be established under national law of a Member State and have legal personality.
2、合格评定机构应依据成员国法律设立，并具有法人身份。

3. A conformity assessment body shall be a third-party body independent of the organisation or the pressure equipment or assembly it assesses.
3、合格评定机构应为独立于组织或评定的压力设备或组合件的第三方组织。

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of pressure equipment or assemblies which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.
属于商业协会或专业协会代表，参与设计、制造、提供、装配、使用或维修的压力设备或组合件的机构，当它评定该设备时，如证明其独立性并且没有任何利益冲突，可以考虑作为评定机构。

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the pressure equipment or assembly which they assess, nor the representative of any of those parties.
4、合格评定机构、其高级管理层和负责实施该合格评定任务的人员不应是他们评定压力设备或组合件的设计师、制造商、供应商、安装者、采购商、业主、用户或维修师，也不能是这些组织的代表。

This shall not preclude the use of assessed pressure equipment or assemblies that are necessary for the operations of the conformity assessment body or the use of such equipment for personal purposes. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that pressure equipment or assembly, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.
这不排除出于合格评定机构运作的需要，使用被评估的压力设备或组合件；或出于个人目的使用上述产品。合格评定机构、其高级管理层和负责实施合格评定的工作人员不得直接参与压力设备或组合件的设计、制造、施工、销售、安装、使用或维修，或代表当事人从事这些活动。他们不得从事任何可能与他们判断的独立性，或被公告的合格评定活动的完整性相冲突的活动。特别针对于咨询服务。

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.
合格评定机构应确保其子公司或分包商的活动不影响他们合格评定活动的保密性、客观性和公正性。

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements,

particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
5、合格评定机构及其人员应当以最高程度的专业诚信和特定领域必备的技术能力进行合格评定行为。并应排除所有的，特别是财务方面的，可能会影响他们合格评定行为判断和结果的压力和刺激，特别是考虑到和该评定结果有利益往来的人或团体。

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 14 or Article 15, or points 3.1.2 and 3.1.3 of Annex I and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.
6、合格评定机构应能执行分配给它的所有第 14 条或第 15 条，或附录 I 第 3.1.2 和 3.1.3 点规定的与它已公告的合格评定任务，不管这些任务是否由合格评定机构本身或其名义进行的，并应对其负责。

At all times and for each conformity assessment procedure and each kind or category of pressure equipment in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:
在任何时候，对于每一个合格评定程序和每一个已公告的压力设备类型，合格评定机构应能处理必要的：

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
（a）有技术知识，并有足够和合适的经验来执行合格评定任务的人员；

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a conformity assessment body and other activities;
（b）根据某种合格评定程序的说明，确保其透明度和程序的再现性。有恰当的政策和程序来区分作为合格评定机构执行的任务或是其他活动；

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
（c）实施活动的程序应考虑到企业大小、操作部门、结构、产品技术问题的复杂程度、大规模或连续生产流程的特性。

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.
合格评定机构应有必要的方式，以适当的行为来实施合格评定活动相关的技术和管理任务，并有必要获得所有必要的设备或设施。

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:
(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
7、负责实施合格评定任务的人员应具备：
（a）涵盖了所有有关合格评定机构已公告的合格评定活动的完善技术和职业培训。
（b）对进行的评定要求有充分的了解，并有足够的权力进行这些评定；
（c）对附录 I 的基本安全要求，适用的协调标准和相关欧盟及国家法规有必要的知识和了解；
（d）有能力编制证明评定已进行的证书、记录和报告。

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.
8、应保证合格评定机构、高级管理层和执行合格评定任务负责人的公正性。

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.
合格评定机构高级管理层和执行合格评定任务负责人的报酬不应取决于检验的次数，也不应该取决于检验结果。

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
9、合格评定机构应当承担责任保险，除非根据国家法律责任由国家承担，或成员国本身直接负责合格评定。

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 14, Article 15, or under points 3.1.2 and 3.1.3 of Annex I or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
10、合格评定机构的人员必须遵守职业保密制度，所有根据第 14 条、第 15 条，附录 I 第 3.1.2 和 3.1.3 点，或任何国家有效的法律条款行使职责时所收集的信息必须保密，除非接受国家行政权力机构的调查。私有权应予以保护。

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible

for carrying out conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.
11、合格评定机构应当参与，或者确保其负责实施合格评定任务的人员得到相关标准化活动和依据相关欧盟协调法规设立的公告机构协调组织活动的通知，并应作为一般性指导原则，采纳该组织工作所实施的行政决定和文件。

Article 25
第 25 条
Requirements relating to user inspectorates
有关用户检验机构的要求

1. For the purposes of notification, a user inspectorate shall meet the requirements laid down in paragraphs 2 to 11.
1、公告的目的在于用户检验机构应符合第 2 到 11 段的要求。

2. A user inspectorate shall be established under national law of a Member State and have legal personality.
2、用户检验机构应依据成员国国家法律成立，并具有法人身份。

3. A user inspectorate shall be organisationally identifiable and have reporting methods within the group of which it is part which ensure and demonstrate its impartiality.
3、用户检验机构应在组织上可识别，并且有向作为一部分的集团报告的方法，以保证和证明其公正性。

4. A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the pressure equipment or assembly which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed pressure equipment or assemblies that are necessary for the operations of the user inspectorate or the use of such equipment for personal purposes.
4、用户检验机构、高级管理层和负责实施该合格评定任务的人员不应是他们评定压力设备或组合件的设计师、制造商、供应商、安装者、采购商、业主、用户或维修师，也不能是这些组织的代表。这不排除出于合格评定机构运作的需要，使用被评估的压力设备或组合件，或出于个人目的使用上述产品。

A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that pressure equipment or assembly, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

用户检验机构、高级管理层和负责实施合格评定的工作人员不得直接参与压力设备或组合件的设计、制造、施工、销售、安装、使用或维修，或代表当事人从事这些活动。他们不得从事任何可能与他们判断的独立性，或他们被公告的合格评定活动的完整性相冲突的活动。特别针对于咨询服务。

5. User inspectorates and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
5、用户检验机构及其人员应当以最高程度的专业诚信和特定领域必备的技术能力进行合格评定行为。并应排除所有的、特别是财务方面的，可能会影响他们合格评定行为判断和结果的压力和刺激，特别是考虑到和该评定结果有利益往来的人或团体。

6. A user inspectorate shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 16 and in relation to which it has been notified, whether those tasks are carried out by the user inspectorate itself or on its behalf and under its responsibility.
6、用户检验机构应能执行分配给它的所有第 16 条规定的与它已公告的合格评定任务，不管这些任务是否由合格评定机构本身或其名义进行的，并应对其负责。

At all times and for each conformity assessment procedure and each kind or category of pressure equipment in relation to which it has been notified, the user inspectorate shall have at its disposal the necessary:
在任何时候，对于每一个合格评定程序和每一个已公告的压力设备类型，用户检验机构应能处理必要的：

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
（a）有技术知识，并有足够和合适的经验来执行合格评定任务的人员；

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a user inspectorate and other activities;
（b）根据某种合格评定程序的说明，确保其透明度和程序的再现性。有恰当的政策和程序来区分作为合格评定机构执行的任务或是其他活动；

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
（c）实施行为的程序应考虑到企业大小、操作部门、结构、产品技术问题的复杂程度、大规模或连续生产流程的特性。

A user inspectorate shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.
用户检验机构应有必要的方式，以适当的行为来实施合格评定活动相关的技术和管理任务，并有必要获得所有必要的设备或设施。

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:
(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
7、负责实施合格评定任务的人员应具备：
（a）涵盖了所有有关合格评定机构已公告的合格评定活动的完善技术和职业培训。
（b）对进行的评定的要求有充分的了解，并有足够的权力进行这些评定；
（c）对附录 I 的基本安全要求，适用的协调标准和相关欧盟及国家法规有必要的知识和了解；
（d）有能力编制证明评定已进行的证书、记录和报告。

8. The impartiality of the user inspectorates, their top level management and of the personnel responsible for carrying out conformity assessment tasks shall be guaranteed. User inspectorates must not engage in any activities that might conflict with its independence of judgement and integrity in relation to its inspection activities.
8、应保证用户检验机构、高级管理层和执行合格评定任务负责人的公正性。用户检验机构不得从事任何可能与他们判断的独立性，或检验活动的完整性相冲突的活动。

The remuneration of the top level management and personnel responsible for carrying out conformity assessment tasks of a user inspectorate shall not depend on the number of assessments carried out or on the results of those assessments.
用户检验机构高级管理层和执行合格评定任务负责人的报酬不应取决于检验的次数，也不应该取决于检验结果。

9. User inspectorates shall take out liability insurance unless liability is assumed by the group of which they are part.
9、用户检验机构应当承担责任保险，除非是由他们作为一部分的集团承担。

10. The personnel of user inspectorates shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 16 or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in

which its activities are carried out. Proprietary rights shall be protected.
10、用户检验机构的人员必须遵守职业保密制度，所有根据第 16 条或任何国家有效的法律条款行使职责时所收集的信息必须保密，除非接受国家行政权力机构的调查。私有权应予以保护。

11. User inspectorates shall participate in, or ensure that their personnel responsible for carrying out conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.
11、用户检验机构应当参与，或者确保其负责实施合格评定任务的人员得到相关标准化活动和依据相关欧盟协调法规设立的公告机构协调组织活动的通知，并应作为一般性指导原则，采纳该组织工作所产生的行政决定和文件。

Article 26
第 26 条
Presumption of conformity of conformity assessment bodies
合格评定机构符合的推定

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article 24 or Article 25 in so far as the applicable harmonised standards cover those requirements.
当合格评定机构证明其符合相关已在欧盟官方杂志上发表的参考协调标准或其部分的规定时，应推定该机构目前满足第 24 或 25 条规定的要求，因为适用的协调标准涵盖这些要求。

Article 27
第 27 条
Subsidiaries of and subcontracting by conformity assessment bodies
合格评定机构的子公司和分包

1. Where a notified body, a user inspectorate or a recognised third-party organisation subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 or Article 25 and shall inform the notifying authority accordingly.
1、当公告机构（Notified Body，如阿拜维 APAVE）、用户检验机构或认可的第三方组织分包与合格评定有关的特定任务或依赖子公司时，应确保分包商或子公司符合第 24 条或第 25 条规定的要求，并应通知相应公告主管机构。

2. Notified bodies, user inspectorates and recognised third-party organisations shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
2、无论这些公司设立在哪里，公告机构、用户检验机构和认可第三方组织承担分包商或子

公司执行任务的全部责任。

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
3、只有与客户达成协议的情况下，可由分包商或子公司进行活动。

4. Notified bodies, user inspectorates and recognised third-party organisations shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 14, Article 15, Article 16 or points 3.1.2 and 3.1.3 of Annex I.
4、公告机构、用户检验机构和认可第三方组织应当按公告主管机构处理，保存关于评定分包商或子公司资格和分包机构依据第 14 条，第 15 条，第 16 条或附录 I 第 3.1.2 和 3.1.3 点进行活动的有关文件。

Article 28
第 28 条
Application for notification
公告的申请

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
1、合格评定机构应当在公司成立所在的成员国，向当地公告主管机构提交公告申请。

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the pressure equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24 or Article 25.
2、公告的申请应附有合格评定活动的描述、合格评定的模式、该机构声明负责的压力设备，以及如果有，由国家认可机构颁发、证明合格评定机构符合第 24 条或第 25 条要求的认可证书。

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24 or Article 25.
3、当合格评定机构不能提供认可证书时，应当向公告主管机构提供所有必要的证明文件以验证、确认和定期监督其符合第 24 条或第 25 条规定的要求。

Article 29
第 29 条
Notification procedure
公告程序

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24 or Article 25.
1、公告主管机构可以仅公告已符合第 24 条或第 25 条要求的合格评定机构。

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
2、他们应使用由委员会开发和管理的电子公告设备，公告委员会和其他成员国。

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the pressure equipment concerned and the relevant attestation of competence.
3、公告应包括合格评定活动的全部细节、合格评定模式、涉及的压力设备和相关能力的认证。

4. Where a notification is not based on an accreditation certificate as referred to in Article 28(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24 or Article 25.
4、当公告不是以第 28 条第（2）款所指的认可证书为依据，公告主管机构应向委员会和其他成员国提交书面证明，证明合格评定机构的能力。并已安排到位，确保该机构将被定期监控，并持续满足第 24 或 25 条规定的要求。

5. The body concerned may perform the activities of a notified body, a recognised third-party organisation or a user inspectorate only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.
5、被考核机构只有当没有委员会或其他成员国对有认可证书的机构公告在两周内、对没有认可证书的机构公告在两个月内提出异议时，才可以作为公告机构、认可第三方组织或用户检验机构的执行活动。

Only such a body shall be considered a notified body, a recognised third-party organisation or a user inspectorate for the purposes of this Directive.
只有这样的机构才被视为本指令所要的公告机构、认可第三方组织或用户检验机构。

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.
6、公告主管机构应公告委员会和其他成员国任何公告的变更。

Article 30
第 30 条
Identification numbers and lists of notified bodies
公告机构识别编码及列表

1. The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several Union acts.
1、委员会应将分配给公告机构（Notified Body，如阿拜维 APAVE）一个识别编码。即使机构被多个欧盟法令所公告，也仅会被分到一个单独的识别编码。

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall ensure that the list is kept up to date.
2、委员会应公布符合本指令的公告机构（Notified Body，如阿拜维 APAVE）的名单，包括已分配给他们的识别编码和已公告的行为。委员会应确保该名单随时更新。

Article 31
第 31 条
Lists of recognised third-party organisations and user inspectorates
认可第三方组织和用户检验机构列表

The Commission shall make publicly available the list of the recognised third-party organisations and of the user inspectorates under this Directive and the tasks for which they have been recognised. The Commission shall ensure that the list is kept up to date.
委员会应公开符合本指令的认可第三方组织和用户检验机构名单，包括已被认可的任务。委员会应确保该名单随时更新。

Article 32
第 32 条
Changes to notifications
公告的变更

1. Where a notifying authority has ascertained or has been informed that a notified body or a recognised third-party organisation no longer meets the requirements laid down in Article 24 or that it is failing to fulfil its obligations, the notifying authority shall, as appropriate, restrict, suspend or withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
1、当公告主管机构已确定或已被告知某公告机构或认可第三方组织不再符合第 24 条规定的要求，或其未履行其义务时，公告主管机构应视其未能满足要求或履行义务的严重性，酌情限制、中止或撤回公告。它应立即通知委员会和其他相关成员国。

Where a notifying authority has ascertained or has been informed that a user inspectorate no longer meets the requirements laid down in Article 25, or that it is failing to fulfil its obligations, the notifying authority shall as appropriate, restrict, suspend or withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
在公告主管机构已确定或已被告知用户检验机构不再符合第 25 条规定的要求，或未履行其义务时，公告主管机构应视其未能满足要求或履行义务的严重性，酌情限制、中止或撤回公

告。它应立即通知委员会和其他相关成员国。

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body, the recognised third-party organisation or the user inspectorate has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body, recognised third-party organisation or user inspectorate, or kept available for the responsible notifying and market surveillance authorities at their request.
2、在限制、中止或撤回公告的情况下，或公告机构（Notified Body，如阿拜维 APAVE）、认可第三方组织或用户检验机构已停止其活动，公告成员国应采取适当的措施，以确保该机构的文件交由另一个公告机构（Notified Body，如阿拜维 APAVE）、认可第三方组织或用户检验机构处理，或在负责公告和市场监管部门的要求下供查阅。

Article 33
第 33 条
Challenge of the competence of notified bodies, recognised third party organisations and user inspectorates
对公告机构（Notified Body，如阿拜维 APAVE）、认可第三方组织和用户检验机构能力的质疑

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body, a recognised third-party organisation or a user inspectorate, or the continued fulfilment by a notified body, a recognised third-party organisation or a user inspectorate of the requirements and responsibilities to which it is subject.
1、委员会应调查所有它怀疑的，或各方怀疑引起了它关注的公告机构、认可第三方组织或用户检验机构能力，或者公告机构、认可第三方组织或用户检验机构持续满足它管辖范围内的要求和责任的案例。

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the conformity assessment body concerned.
2、公告成员国应向委员会提供有关所有要求的、有关公告基础或被考察的合格评定机构保持能力的信息。

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
3、委员会应确保所有在其调查过程中获得的敏感信息都被保密处理。

4. Where the Commission ascertains that a notified body, a recognised third-party organisation or a user inspectorate does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 44(2).
4、当委员会确定公告机构（Notified Body，如阿拜维 APAVE）、认可第三方组织或用户检验机构不符合或者不再符合公告要求时，应实施法令，要求公告成员国采取必要的，如有必要，

包括撤回公告的纠正措施。实施法令应遵从第 44 条第（2）款所指的咨询程序。

Article 34
第 34 条
Operational obligations of notified bodies, user inspectorates and recognised third party organisations
公告机构、用户检验机构和认可第三方组织的运营义务

1. Notified bodies, user inspectorates and recognised third-party organisations shall carry out conformity assessments in accordance with the conformity assessment tasks provided for in Article 14, Article 15, Article 16, or in points 3.1.2 and 3.1.3 of Annex I.
1、公告机构、用户检验机构和认可第三方组织应依据第 14 条、第 15 条、第 16 条或附录 I 第 3.1.2 和 3.1.3 点提供的合格评定任务来进行合格评定。

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.
2、合格评定应以适当的方式进行，避免运营商不必要的负担。

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the pressure equipment or assembly technology in question and the mass or serial nature of the production process.
合格评定机构履行其活动时应考虑到企业大小、操作部门、结构、产品技术问题的复杂程度、大规模或连续生产流程的特性。

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the pressure equipment with the requirements of this Directive.
在这样做时，他们仍应尊重本指令要求的满足压力设备要求的严谨程度和保护等级。

3. Where a conformity assessment body finds that essential safety requirements set out in Annex I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.
3、当合格评定机构发现制造商未能满足附录 I 所规定的基本安全要求或相应的协调标准或其他技术规范时，应要求制造商采取适当的纠正措施，并不得颁发合格证书。

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a conformity assessment body finds that pressure equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
4、在证书颁布后的认证监管中，当合格评定机构发现压力设备不再符合规定时，应要求制造商采取适当的纠正措施，如有必要，应中止或撤销证书。

5. Where corrective measures are not taken or do not have the required effect, the conformity

assessment body shall restrict, suspend or withdraw any certificates, as appropriate.
5、未采取纠正措施或者没有达到规定效果的，合格评定机构应酌情限制、中止或撤回任何证书。

Article 35
第 35 条
Appeal against decisions of notified bodies, recognised third party organisations and user inspectorates
对公告机构、认可第三方组织和用户检验机构决定的上诉

Member States shall ensure that appeal procedures against decisions of notified bodies, recognised third-party organisations and user inspectorates are available.
成员国应确保有反对公告机构、认可第三方组织和用户检验机构决定的上诉程序。

Article 36
第 36 条
Information obligation on notified bodies, recognised third party organisations and user inspectorates
公告机构、认可第三方组织和用户检验机构决定的通知义务

1. Notified bodies, recognised third-party organisations and user inspectorates shall inform the notifying authority of the following:
1、公告机构、认可第三方组织和用户检验机构应通知公告主管机构以下信息：

(a) any refusal, restriction, suspension or withdrawal of a certificate;
(b) any circumstances affecting the scope of or conditions for notification;
(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
（a）任何证书的拒绝、限制、暂停或撤回；
（b）影响公告范围或条件的任何情况；
（c）任何他们收到市场监管当局要求的有关有关评定活动的资料；
（d）如有要求，他们的公告范围内的合格评定活动和任何其他活动，包括跨境活动和分包。

2. Notified bodies, recognised third-party organisations and user inspectorates shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same pressure equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.
2、公告机构、认可第三方组织和用户检验机构应为本指令其他公告机构在同一压力设备上进行类似的合格评定活动提供有关负面的和正面的（如要求）合格评定结果的相关信息。

Article 37
第 37 条

Exchange of experience
经验交流

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.
委员会应为成员国负责公告政策的国家主管机构之间提供经验交流组织。

Article 38
第 38 条
Coordination of notified bodies, recognised third-party organisations and user inspectorates
公告机构、认可第三方组织和用户检验机构的协调

The Commission shall ensure that appropriate coordination and cooperation between the conformity assessment bodies notified under this Directive are put in place and properly operated in the form of a sectoral group or groups of conformity assessment bodies.
委员会应确保该指令合格评定机构之间进行适当的协调与合作，并以合格评定机构的组织或部门组织形式妥善运营。

Member States shall ensure that the conformity assessment bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.
成员国应确保他们公告的合格评定机构直接或通过指定的代表参与这些组织。

CHAPTER 5
第 5 章
UNION MARKET SURVEILLANCE, CONTROL OF PRESSURE EQUIPMENT AND ASSEMBLIES ENTERING THE UNION MARKET, AND UNION SAFEGUARD PROCEDURE
欧盟市场监控，控制压力设备和组合件进入欧盟及欧盟保障程序
Article 39
第 39 条
Union market surveillance and control of pressure equipment and assemblies entering the Union market
欧盟市场对压力设备和组合件进入欧盟市场的监控

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to pressure equipment and assemblies covered by Article 1 of this Directive.
No 765/2008 法规第 15 条第（3）款和第 16 至第 29 条应施用于本指令第 1 条所涵盖的压力设备和组合件。

Article 40
第 40 条
Procedure for dealing with pressure equipment or assemblies presenting a risk at national level
国家层级处理压力设备或组合件产生风险的程序

1. Where the market surveillance authorities of one Member State have sufficient reasons to

believe that pressure equipment or assemblies covered by this Directive present a risk to the health or safety of persons or to domestic animals or property, they shall carry out an evaluation in relation to the pressure equipment or assembly concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.
1、当成员国市场监管机构有充分理由相信本指令涵盖的压力设备或组合件对人或动物或财产的健康或安全产生风险时，应依据本指令规定的所有相关要求，对相关压力设备或组合件进行评定。相关经营者应当为此配合市场监管机构。

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the equipment or assembly does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the pressure equipment or assembly into compliance with those requirements, to withdraw the equipment or assembly from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.
当第一个段所指的评价过程中，当市场监管机构发现该设备或组合件不符合本指令规定要求时，应立即要求相关经营者根据风险性质，采取一切适当的纠正措施，使压力设备或组合件成满足这些要求，或从市场上撤回设备或组合件，或如他们指定，在一个合理期限内召回设备。

The market surveillance authorities shall inform the relevant notified body accordingly.
市场监管机构应通知有关公告机构。

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.
(EC) No 765/2008 规定的第 21 条规定了本条第二段提及的措施。

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.
2、当市场监管机构认为该不符合项在他们国家范围内不受限制，他们应通知委员会和其他成员国的评定结果及他们要求运营商采取的措施。

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the pressure equipment and assemblies concerned that it has made available on the market throughout the Union.
3、经营者应确保所有已投入整个欧盟市场的压力设备和组合件都采取适当的纠正措施。

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the equipment's or assembly's being made available on their national market, to withdraw the equipment or

assembly from that market or to recall it.
4、当相关经营者未能在第一段第二小节提到的时间范围内采取适当的纠正措施，市场监管机构应当采取一切适当的临时措施，禁止或限制设备或组合件在他们国家市场上使用，并从市场上撤回或召回的该设备或组合件。

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.
市场监管机构应及时向委员会和其他成员国通报该措施。

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant equipment or assembly, the origin of the equipment or assembly, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:
5、第 4 段第二节提到的资料应包括所有可用的资料，特别是确定不符合的设备或组合件、设备或组合件来源、不符合涉及的特性和所涉及风险、国家采取措施的性质和持续时间，以及有关经营者提出依据的必要数据。特别是市场监管机构应表明不符合项是否为以下任一项：

(a) failure of the equipment or assembly to meet requirements relating to the health or safety of persons or to the protection of domestic animals or property; or
（a）设备或组合件不足以满足有关人士健康或安全，或保护国内动物或财产的要求。

(b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.
（b）在第 12 条合格假定协调标准的不足。

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the equipment or assembly concerned, and, in the event of disagreement with the adopted national measure, of their objections.
6、除本条规定成员国以外的成员国应立即通知委员会和其他成员国任何采纳的措施和任何他们处理相关不符合设备或组合件的额外信息，并在反对已被采纳的国家措施时，提出他们的反对意见。

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.
7、当收到第 4 段第二节提到的信息三个月内，没有任何一个成员国或委员会对该成员国采取的临时措施提出反对意见时，该措施即被认为是合理的。

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the equipment or assembly from the market, are taken in respect of the equipment or assembly concerned without delay.
8、成员国应考虑到相关设备或组合件，确保立即采取适当的限制性措施，如将设备或组合件从市场上撤回。

Article 41
第 41 条
Union safeguard procedure
欧盟保障程序

1. Where, on completion of the procedure set out in Article 40(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.
1、当第 40 条第（3）及（4）款所指的程序完成时，若成员国采取的措施被反对，或委员会认为该国家措施违反欧盟法律，委员会应立即与各成员国和相关经营者评定该国家措施。依据评价结果，委员会应实施法案，确定该国家措施是否合理。

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.
委员会应告知所有成员国其决定，并立即与成员国及相关经营者沟通。

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant equipment or assembly is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.
2、若国家措施被认为是合理的，所有成员国应采取必要的措施，确保不符合规定的设备或组合件撤出市场，并相应地通知委员会。如果该国家措施被认为是不合理的，有关成员国应取消该措施。

3. Where the national measure is considered justified and the non-compliance of the equipment or assembly is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 40(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.
3、当该国家措施被认为是合理的，不符合规定的设备或组合件是由于本指令第 40 条第 5 款（b）点的协调标准不足而引起的，委员会应采取(EU) No 1025/2012 法规第 11 条规定的程序。

Article 42
第 42 条
Compliant pressure equipment or assemblies which present a risk

合格压力设备或组合件出现风险

1. Where, having carried out an evaluation under Article 40(1), a Member State finds that although pressure equipment or an assembly is in compliance with this Directive, it presents a risk to the health or safety of persons, to domestic animals or property, it shall require the relevant economic operator to take all appropriate measures to ensure that the equipment or assembly concerned, when placed on the market, no longer presents that risk, to withdraw the equipment or assembly from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.
1、当根据第 40 条第（1）款进行评定，成员国发现虽然压力设备或组合件符合本指令要求，但依然表现出对人员健康或安全、国内动物或财产风险时，应要求相关经营者采取一切适当措施，确保投放在市场上的设备或组合件不再出现该风险，或如它规定的，在一个合理的时段内，根据适应的风险性质，将撤出或召回市场上的设备或组合件。

2. The economic operator shall ensure that corrective action is taken in respect of all the equipment or assemblies concerned that he has made available on the market throughout the Union.
2、经营者应确保对所有在整个欧盟市场上的相关设备或组合件采取纠正措施。

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the equipment or assembly concerned, the origin and the supply chain of the equipment or assembly, the nature of the risk involved and the nature and duration of the national measures taken.
3、成员国应立即通知委员会和其他成员国。这些信息应包括所有可用的细节，特别是特别是确定不符合的设备或组合件、设备或组合件来源、不符合涉及的特性和所涉及风险、国家采取措施的性质和持续时间。

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.
4、委员会应立即与各成员国和相关运营商评定所采取的国家措施。在该评价结果基础上，委员会应通过实施法规来决定国家措施是否合理，当有必要时，提出适当的措施。

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).
本段第一节所指的实施法规，应依照第 44 条第（3）款的检查程序执行。

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, or of domestic animals or of property, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).
若出于保护人员健康和安全、国内动物或财产的原因，有充分、合理且必要的急迫理由，委

员会应根据第 44 条第（4）款所指的程序，立即采取适宜的实施法规。

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.
5、委员会应向所有成员国通知其决定，并立即与各成员国与相关经营者沟通。

Article 43
第 43 条
Formal non-compliance
正式不符合

1. Without prejudice to Article 40, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
1、不违背第 40 条的情况下，当成员国发现以下之一情况时，它应要求相关经营者停止相关不符合项：

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 19 of this Directive;
（a）CE 标识违反(EC) No 765/2008 法规第 30 条或本指令第 19 条的规定；
(b) the CE marking has not been affixed;
（b）未粘贴 CE 标识；
(c) the identification number of the notified body involved in the production control phase, has been affixed in violation of Article 19 or has not been affixed;
（c）在涉及生产控制阶段的公告机构识别号，未按照第 19 条要求粘贴，或未被粘贴；
(d) the marking and labelling referred to in point 3.3. of Annex I have not been affixed or have been affixed in violation of Article 19 or point 3.3 of Annex I;
（d）未粘贴附录 I 第 3.3 点所指的标识和标签或违反第 19 条或附录 I 第 3.3 条要求粘贴；
(e) the EU declaration of conformity has not been drawn up;
（e）没有制定欧盟符合性声明；
(f) the EU declaration of conformity has not been drawn up correctly;
（f）未能正确地制定欧盟符合性声明；
(g) the technical documentation is either not available or not complete;
（g）技术文件不可行或不完整；
(h) the information referred to in Article 6(6) or Article 8(3) is absent, false or incomplete;
（h）第 6 条第（6）款或第 8 条第（3）款所指的信息不存在、虚假或不完整；
(i) any other administrative requirement provided for in Article 6 or Article 8 is not fulfilled.
（i）其他未能满足第 6 条或第 8 条规定的行政要求。

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the equipment or assembly being made available on the market or ensure that it is recalled or withdrawn from the market.
2、当第 1 段所指的不符合项存在时，相关成员国应当采取一切适当的措施，限制或禁止设备或组合件在市场上流通，或确保设备被召回或退出市场。

CHAPTER 6
第 6 章
COMMITTEE PROCEDURE AND DELEGATED ACTS
委员会程序和授权法规
Article 44
第 44 条
Committee procedure
委员会程序

1. The Commission shall be assisted by the Committee on Pressure Equipment. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
1、委员会应受压力设备委员会的协助。该委员会应是(EU) No 182/2011 法规所指的委员会。

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
2、本段参考的文件，适用于(EU) No 182/2011 法规第 4 条。

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3、本段参考的文件，适用于(EU) No 182/2011 法规第 5 条。

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.
4、本段参考的文件，适用于(EU) No 182/2011 法规关于第 5 条的第 8 条内容。

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.
5、委员会应就任何有关部门专家的咨询意见，由委员会咨询
要求由监管(EU) No 1025/2012 法规或其他任何欧盟法律。

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
该委员会可进一步检查由主席或成员国代表根据其程序规则提出的、有关本指令应用的任何其他事项。

Article 45
第 45 条
Delegated power
授予的权力

1. In order to take into account emerging very serious safety reasons, the Commission shall be empowered to adopt delegated acts in accordance with Article 46 reclassifying pressure equipment or assemblies so as to:

1、考虑到新出现的非常严重的安全因素，委员会应被授权依照第 46 条对压力设备或组合件重新分类并发布法规：

(a) make an item or family of pressure equipment referred to in Article 4(3) subject to the requirements of Article 4(1);
（a）根据第 4 条第（1）款要求，为第 4 条第（3）款所指的压力设备设立一个项或族；

(b) make an assembly or family of assemblies referred to in Article 4(3) subject to the requirements of Article 4(2);

（b）根据第 4 条第（2）款要求，为第 4 条第（3）款所指的压力组合件设立一个组合件项或组合件族；

(c) classify an item or family of pressure equipment, by way of derogation from the requirements of Annex II, in another category.
（c）通过降低附录 II 要求，在另一个类中为压力设备分项或族。

2. A Member State having concerns about the safety of pressure equipment or assemblies shall immediately inform the Commission of its concerns and provide reasons in support.
2、对压力设备或组合件安全性有顾虑的成员国，应立即通知委员会该顾虑，并提供理由以支持该观点。

3. Prior to adopting a delegated act the Commission shall carry out a thorough assessment of the risks that require reclassification.
3、在采纳授权行为前，委员会应对需要重新分类的风险进行彻底评估。

Article 46
第 46 条
Exercise of the delegation
授权行使

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
1、采纳授权法案的权力应由委员会根据本条的条件商议。

2. The power to adopt delegated acts referred to in Article 45 shall be conferred on the Commission for a period of five years from 1 June 2015. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
2、在第 45 条中所指的采纳授权法案的权力，应由委员会在 2015 年 6 月 1 日起的五年内商议。委员会应在不迟于五年期结束前的九个月对授权的权力发布一份报告。授权的权力应默许延长相同的期限，除非欧洲议会或理事会在不迟于每个时期结束之前三个月反对这种延期。

3. The delegation of power referred to in Article 45 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
3、在第 45 条中提到的权力可能会在任何时间被欧洲议会或理事会撤销。撤销决定应当终止该决定所规定的权力。决定应在欧洲欧盟官方杂志发表或稍后指定的日期生效。它不影响任何已生效授权法案的有效性。

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
4、一旦采纳了授权法案，委员会应同时通知欧洲议会和理事会。

5. A delegated act adopted pursuant to Article 45 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.
5、根据第 45 条所采取的授权法案，只有在该法规公告给欧洲议会或理事会两个月后，欧洲议会或理事会没有表示异议，或在这段期间结束前，欧洲议会和理事会都向委员表示他们不会反对时才应生效。在欧洲议会或理事会主动要求下，该期限应延长两个月。

CHAPTER 7
第 7 章
TRANSITIONAL AND FINAL PROVISIONS
过渡和最终条款
Article 47
第 47 条
Penalties
处罚

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. Such rules may include criminal penalties for serious infringements.
各成员国应制定规定适用于运营者违背依照本指令时采取的国家法律条款的行为，并应采取一切必要的措施，确保法规的实施。该规定可包括严重违反行为的刑事处罚。

The penalties referred to in the first paragraph shall be effective, proportionate and dissuasive.
第一段提及的处罚应有效、适度和有说服力。

Article 48

第 48 条
Transitional provisions
过渡性条文

1. Member States shall not impede the putting into service of pressure equipment and assemblies which comply with the regulations in force in their territory at the date of application of Directive 97/23/EC and were placed on the market until 29 May 2002.
1、成员国不得妨碍在 97 / 23 /EC 指令实施时，已符合其领域强制规定的，并在 2002 年 5 月 29 日前投入市场的压力设备和组合件投入使用。

2. Member States shall not impede the making available on the market and/or the putting into service of pressure equipment or assemblies covered by Directive 97/23/EC which are in conformity with that Directive and which were placed on the market before 1 June 2015.
2、会员国不得妨碍 97 / 23 /EC 指令所涵盖的，符合该指令并在 2015 年 6 月 1 日前投放市场的压力设备或组合件进入市场和/或投入使用。

3. Certificates and decisions issued by conformity assessment bodies under Directive 97/23/EC shall be valid under this Directive.
3、合格评定机构根据 97 / 23 /EC 指令颁发的证书和决定，应在本指令下有效。

Article 49
第 49 条
Transposition
流通

1. Member States shall adopt and publish, by 28 February 2015, the laws, regulations and administrative provisions necessary to comply with Article 13. They shall forthwith communicate the text of those measures to the Commission.
1、成员国应在 2015 年 2 月 28 日采取并公布符合第 13 条的必要的法律、法规和行政规定。他们应立即与委员会交流该措施的文本。

They shall apply those measures from 1 June 2015.
他们应自 2015 年 6 月 1 日起实施这些措施。

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to Article 9 of Directive 97/23/EC shall be construed as references to Article 13 of this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.
当成员国采纳这些措施时，他们应引用该指令或在官方正式发布时附上该引用。还应包括一份声明，说明现有法律、规定、行政条例引用 97/23/EC 指令第 9 条的，应引用本指令第 13 条。成员国应确定引用如何实施，及该声明应如何制定。

2. Member States shall adopt and publish, by 18 July 2016, the laws, regulations and administrative provisions necessary to comply with Article 2(15) to (32), Articles 6 to 12, 14, 17 and 18, Article 19(3) to (5), Articles 20 to43, 47 and 48 and Annexes I, II, III and IV. They shall forthwith communicate the text of those measures to the Commission.
2。成员国应在 2016 年 7 月 18 日采纳并公布必要的法律、法规和行政条例以符合第 2 条第（15）到（32）款，第 6 至 12 条，第 14，18 和 17 条，第 19 条（3）至（5）款，第 20 至 43 条、第 47 条、第 48 条，以及附录 I，II，III 和 IV。他们应立即通知委员会这些措施的文本。

They shall apply those measures from 19 July 2016.
他们应自 2016 年 7 月 19 日起采取这些措施。

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.
当成员国采纳这些措施时，他们应包含该指令作为参考或伴在官方发布之际附上该指令参考。还应包括一份声明，在现有的法律、规定和行政法规参考，本指令废止的指令的应被解释为这个指令。成员国应确定如何编写该参考，以及如何制定该声明。

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field governed by this Directive.
3、成员国应向委员会传达他们在本指令管辖范围内采取所规定的国家法律主要法规的文本。

Article 50
第 50 条
Repeal
废除

Article 9 of Directive 97/23/EC is deleted with effect from 1 June 2015, without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and the date of application of that Article, set out in Annex V, Part B.
97/23/EC 指令第 9 条被删除，自 2015 年 6 月 1 日起生效，不违背成员国关于转换为国家法律的时间限制以及该条在附录 V，B 部分的启用日期。

Directive 97/23/EC, as amended by the acts listed in Annex V, Part A, is repealed with effect from 19 July 2016, without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and the date of application of the Directive set out in Annex V, Part B.
97/23/EC 指令，经附录 V，A 部分所列行为的修订，自 2016 年 7 月 19 日起生效，不违背成员国关于转换为国家法律的时间限制以及该条在附录 V，B 部分的启用日期。

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.
废止指令的引用应被指向本指令的引用，并应按照附录 VI 对应的表格解读。

Article 51
第 51 条
Entry into force and application
强制实施与应用

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.
本指令将在欧盟官方杂志出版后第二十天生效。

Article 1, points 1 to 14 of Article 2, Articles 3, 4, 5, 14, 15 and 16, Article 19(1) and (2), and Articles 44, 45 and 46 shall apply from 19 July 2016.
第 1 条，第 2 条第 14 款第 1 点，第 3 条，第 4 条，第 5 条，第 14 条，第 15 条，第 16 条，第 19 条第（1）和（2）款，第 44 条，第 45 条和第 46 条将于 2016 年 7 月 19 日实施。

Article 52
第 52 条
Addressees
收件方

This Directive is addressed to the Member States.
该指令面向所有成员国。
Done at Brussels, 15 May 2014.
于布鲁塞尔，2014 年 5 月 15 日。
For the European Parliament
欧洲议会
The President
主席
M. SCHULZ
M. SCHULZ
For the Council
理事会
The President
主席
D. KOURKOULAS
D. KOURKOULAS

ANNEX I
附录 I
ESSENTIAL SAFETY REQUIREMENTS
基本安全要求
PRELIMINARY OBSERVATIONS
前期观察

1. The obligations arising from the essential safety requirements listed in this Annex for pressure equipment also apply to assemblies where the corresponding hazard exists.
1、本附录列出的压力设备基本安全要求所产生的义务亦适用于存在相应危险的组合件。

2. The essential safety requirements laid down in this Directive are compulsory. The obligations following from those essential safety requirements apply only if the corresponding hazard exists for the pressure equipment in question when it is used under conditions which are reasonably foreseeable by the manufacturer.
2、本指令规定的基本安全要求是强制性的。这些基本安全要求之后的义务只有当压力设备在制造商合理可预见的使用条件下，存在相应危险的问题时才适用。

3. The manufacturer is under an obligation to analyse the hazards and risks in order to identify those which apply to his equipment on account of pressure; he shall then design and construct it taking account of his analysis.
3、制造商有义务根据压力对危险和风险进行分析，确定哪些适用于他的设备，之后他应根据他的分析进行设计和施工。

4. The essential safety requirements are to be interpreted and applied in such a way as to take account of the state of the art and current practice at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection.
4、基本安全要求应以这样一种方式解释和应用：在设计和制造阶段考虑艺术和当前实际的同时，兼顾技术与经济，并坚持高度的健康和安全保护。

1. GENERAL
1、一般要求

1.1. Pressure equipment shall be designed, manufactured and checked, and if applicable equipped and installed, in such a way as to ensure its safety when put into service in accordance with the manufacturer's instructions, or in reasonably foreseeable conditions.
1.1、压力设备应在设计，制造和检查，装备（如适用）和安装时，确保其依据制造商的说明，或在可预见的合理条件下安全使用。

1.2. In choosing the most appropriate solutions, the manufacturer shall apply the principles set out below in the following order:
1.2、在选择最合适的解决方案时，制造商应采用下面所列的原则：

— eliminate or reduce hazards as far as is reasonably practicable;
——尽可能合理和切实可行地消除或减少危险；
— apply appropriate protection measures against hazards which cannot be eliminated;
——对无法消除的危险，采取适当的防护措施；
— where appropriate, inform users of residual hazards and indicate whether it is necessary to take appropriate special measures to reduce the risks at the time of installation and/or use.
——在适当情况下，告知使用者的残留危害，并指示是否在安装和/或使用时有必要采取适当的特殊措施以减少风险。

1.3. Where the potential for misuse is known or can be clearly foreseen, the pressure equipment shall be designed to prevent risks from such misuse or, if that is not possible, adequate warning given that the pressure equipment shall not be used in that way.
1.3、当已知或可以清楚地预见可能潜在被误用时，压力设备应被设计以防误用风险，若不可能，应给予对压力设备不得以该方式使用进行充分警告。

2. DESIGN
2、设计

2.1. General
2.1、概述
The pressure equipment shall be properly designed taking all relevant factors into account in order to ensure that the equipment will be safe throughout its intended life.
压力设备应考虑所有相关因素合理设计，以确保该设备在其预期寿命内安全使用。

The design shall incorporate appropriate safety coefficients using comprehensive methods which are known to incorporate adequate safety margins against all relevant failure modes in a consistent manner.
按照已知结合有效安全边际，以相应防止所有失效模式的综合方法，设计应结合合适的安全系数。

2.2. Design for adequate strength
2.2、设计足够强度
2.2.1. The pressure equipment shall be designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions. In particular, the following factors shall be taken into account:
2.2.1、压力设备应设计适合其预期用途的和其他合理的、可预见操作条件下的负荷。特别应考虑以下因素：

— internal/external pressure,
——内部/外部压力，
— ambient and operational temperatures,
——环境和操作温度，
— static pressure and mass of contents in operating and test conditions,

——在操作和试验条件下的静态压力和质量，
— traffic, wind, earthquake loading,
——由交通、风、地震产生的荷载，
— reaction forces and moments which result from the supports, attachments, piping, etc.,
——由支架、附件、管道等引起的反作用力和力矩，
— corrosion and erosion, fatigue, etc,
——腐蚀和冲蚀、疲劳等，
— decomposition of unstable fluids.
——不稳定流体的分解。

Various loadings which can occur at the same time shall be considered, taking into account the probability of their simultaneous occurrence.
应考虑各种载荷在同一时间发生情况，并考虑他们同时发生的概率。

2.2.2. Design for adequate strength shall be based on either of the following:
2.2.2、应基于以下情形，设计足够强度：

— as a general rule, a calculation method, as described in point 2.2.3, and supplemented if necessary by an experimental design method as described in point 2.2.4,
—— 基本规则是按 2.2.3 所描述的计算方法，以及如果必要的话，补充进行按 2.2.4 所描述的试验设计方法；

— an experimental design method without calculation, as described in point 2.2.4, when the product of the maximum allowable pressure PS and the volume V is less than 6 000 bar.L or the product PS.DN less than 3 000 bar.
——如 2.2.4 描述的无需计算的实验设计方法，当产品的最大允许压力 PS 乘体积 V 小于 6 000 BarxL 或产品的 PS.DN 小于 3000 Bar。

2.2.3. Calculation method
2.2.3、计算方法
(a) Pressure containment and other loading aspects
（a）压力强度和其他载荷方面

The allowable stresses for pressure equipment shall be limited having regard to reasonably foreseeable failure modes under operating conditions. To this end, safety factors shall be applied to eliminate fully any uncertainty arising out of manufacture, actual operational conditions, stresses, calculation models and the properties and behaviour of the material.
考虑到合理的可预见的操作情况下的失效模式，应限制压力设备的允许压力。因此，应采用安全系数，以完全消除由于制造、实际使用、载荷、计算模式、材料特性和性能引起的一切不确定因素。

These calculation methods shall provide sufficient safety margins consistent, where applicable, with the requirements of point 7.
这些计算方法应留有足够的安全余量，并当适用时，与第 7 点要求一致。

The requirements set out above may be met by applying one of the following methods, as appropriate, if necessary as a supplement to or in combination with another method:
上述要求可酌情通过采用以下方法之一满足，如有需要，可补充或结合其他方法：

— design by formula,
——根据公式设计，
— design by analysis,
——根据分析设计，
— design by fracture mechanics.
——根据断裂机理设计。

(b) Resistance
（b）承载性
Appropriate design calculations shall be used to establish the resistance of the pressure equipment concerned.
应使用合适的设计计算，建立相关压力设备的承载性。

In particular:
特别是:

— the calculation pressures shall not be less than the maximum allowable pressures and take into account static head and dynamic fluid pressures and the decomposition of unstable fluids. Where a vessel is separated into individual pressure-containing chambers, the partition wall shall be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjoining chamber,
——计算压力应不得小于最大允许压力，并考虑静态压力和动态流体压力以及不稳定流体分解压力。如果容器被分割成多个压力腔，分隔壁应按腔内可能最大压力相对相邻腔内最小压力设计，

— the calculation temperatures shall allow for appropriate safety margins,
——计算温度应允许适当的安全余量，

— the design shall take appropriate account of all possible combinations of temperature and pressure which might arise under reasonably foreseeable operating conditions for the equipment,
——设计应考虑在合理可预见的操作设备条件下，所有可能的温度和压力组合，

— the maximum stresses and peak stress concentrations shall be kept within safe limits,
——最大应力和峰部应力集中应保持在安全范围内，

— the calculation for pressure containment shall utilise the values appropriate to the properties of the material, based on documented data, having regard to the provisions set out in point 4 together with appropriate safety factors. Material characteristics to be considered, where

applicable, include:
——压力容器的计算应根据记录的数据，考虑第 4 点规定的合适安全因素，使用合适性能的材料。在适用的情况下，应考虑材料特性，包括：
— yield strength, 0,2 % or 1,0 % proof strength as appropriate at calculation temperature,
——根据计算温度，酌情考虑屈服强度、0.2%或 1,0 %弹限强度，
— tensile strength,
——抗拉强度，
— time-dependent strength, i.e. creep strength,
——随时间变化的强度，如蠕变强度，
— fatigue data,
——疲劳数据，
— Young's modulus (modulus of elasticity),
——杨氏模量（弹性模量），
— appropriate amount of plastic strain,
——适当的塑性应变，
— bending rupture energy,
——抗弯断裂能，
— fracture toughness.
——断裂韧性。

— appropriate joint factors shall be applied to the material properties depending, for example, on the type of non-destructive testing, the materials joined and the operating conditions envisaged,
——材料属性时应考虑合适的连接因素以决定例如无损测试类型，材料连接方式和设想的操作条件，

— the design shall take appropriate account of all reasonably foreseeable degradation mechanisms(e.g. corrosion, creep, fatigue) commensurate with the intended use of the equipment. Attention shall be drawn, in the instructions referred to in point 3.4, to particular features of the design which are relevant to the life of the equipment, for example:
——设计应适当考虑所有可合理预见的，与设备预期用途相称的降级机理（如腐蚀、蠕变、疲劳）。应注意 3.4 点提到的说明，特别是与设备寿命有关的设计特征，例如：
— for creep: design hours of operation at specified temperatures,
——蠕变：设计在特定温度下的工作时间，
— for fatigue: design number of cycles at specified stress levels,
——疲劳：设计在特定应力下的周期数，
— for corrosion: design corrosion allowance.
——腐蚀：设计腐蚀余量。

(c) Stability aspects
（C）稳定性
Where the calculated thickness does not allow for adequate structural stability, the necessary measures shall be taken to remedy the situation taking into account the risks from transport and handling.

当计算出的厚度无法提供足够的结构稳定性，考虑到运输和处理的风险，应采取必要的措施来纠正这种情况。

2.2.4. Experimental design method
2.2.4、实验设计法
The design of the equipment may be validated, in all or in part, by an appropriate test programme carried out on a sample representative of the equipment or the category of equipment.
该设备的设计可能会对该设备或该类别的样品实施适当的实验方案，进行全部或部分验证。

The test programme shall be clearly defined prior to testing and accepted by the notified body responsible for the design conformity assessment module, where it exists.
应在测试前清楚地定义实验方案，并被负责设计符合评定模式的公告机构（Notified Body，如阿拜维 APAVE）接受（如存在）。

This programme shall define test conditions and criteria for acceptance or refusal. The actual values of the essential dimensions and characteristics of the materials which constitute the equipment tested shall be measured before the test.
该方案应确定试验接受或拒绝的条件和标准。构成设备的材料的基本尺寸和特性实际值应在试验前测量。

Where appropriate, during tests, it shall be possible to observe the critical zones of the pressure equipment with adequate instrumentation capable of registering strains and stresses with sufficient precision.
在测试允许时，应有足够精密的、可以记录应变和应力的仪器，监测压力设备关键区域。

The test programme shall include:
实验方案应包括：
(a) A pressure strength test, the purpose of which is to check that, at a pressure with a defined safety margin in relation to the maximum allowable pressure, the equipment does not exhibit significant leaks or deformation exceeding a determined threshold.
（a）压力强度测试，其目的是要检查在最大允许压力所确定的安全范围的压力作用下，设备没有出现明显的泄漏或超过临界值的变形。

The test pressure shall be determined on the basis of the differences between the values of the geometrical and material characteristics measures under test conditions and the values used for design purposes; it shall take into account the differences between the test and design temperatures;
试验压力应根据在试验条件下几何尺寸和材料性能的实际测量值与设计使用值的差值确定；同时，应考虑实验和设计温度的差别。

(b) where the risk of creep or fatigue exists, appropriate tests determined on the basis of the service conditions laid down for the equipment, for instance hold time at specified temperatures, number of cycles at specified stress-levels;

（b）当有发生蠕变或疲劳风险时，应根据设备设定的使用条件确定适当的试验，例如在特定温度下保持一段时间，在特定应力等级下循环一定次数；

(c) where necessary, additional tests concerning other factors referred to in point 2.2.1 such as corrosion, external damage.
（c）必要时，涉及到 2.2.1 点的其他因素，如腐蚀、外部损伤的额外测试。

2.3. Provisions to ensure safe handling and operation
2.3、确保安全处理和操作的规定

The method of operation specified for pressure equipment shall be such as to preclude any reasonably foreseeable risk in operation of the equipment. Particular attention shall be paid, where appropriate, to:
压力设备的操作方式应如避免任何可合理预见的设备运行中的风险。应特别注意（如适用）：

— closures and openings,
——关闭和打开装置；
— dangerous discharge of pressure relief blow-off,
——压力释放时排气的危险；
— devices to prevent physical access whilst pressure or a vacuum exists,
——在压力或真空存在时，防止进入的设备；
— surface temperature taking into consideration the intended use,
——考虑预期使用时的表面温度；
— decomposition of unstable fluids.
——不稳定流体的分解。

In particular, pressure equipment fitted with an access door shall be equipped with an automatic or manual device enabling the user easily to ascertain that the opening will not present any risk. Furthermore, where the opening can be operated quickly, the pressure equipment shall be fitted with a device to prevent it being opened whenever the pressure or temperature of the fluid presents a risk.
特别是，带有进入门的压力设备应带有自动或手动装置，可让用户方便地确定开口不会有任何风险。此外，当可以快速操作开口时，压力设备应配备装置，防止在带有流体压力或温度风险时打开设备。

2.4. Means of examination
2.4、验证方式
(a) Pressure equipment shall be designed and constructed so that all necessary examinations to ensure safety can be carried out;
（a）压力设备应设计和制造成可以进行所有必要的、用以确保安全的验证；

(b) Means of determining the internal condition of the equipment shall be available, where it is necessary to ensure the continued safety of the equipment, such as access openings allowing physical access to the inside of the pressure equipment so that appropriate examinations can be

carried out safely and ergonomically;
（b）当有必要确认设备持续安全时，应具备确认设备内部状况的措施，如允许进入压力设备内部的通道开口，以便开展适当的、安全且符合人体工程学的验证；

(c) Other means of ensuring the safe condition of the pressure equipment may be applied in any of the following situations:
（c）其他确保压力设备安全状况的方法可应用于下列任一情况：

— where it is too small for physical internal access,
——太小以至于难以进入内部，
— where opening the pressure equipment would adversely affect the inside,
——打开压力设备会对内部产生不利影响，
— where the substance contained has been shown not to be harmful to the material from which the pressure equipment is made and no other internal degradation mechanisms are reasonably foreseeable.
——所含物质已被证明不会伤害制造压力设备的材料，并且没有其他可合理预见的内部降解机制。

2.5. Means of draining and venting
2.5、排水和通风装置
Adequate means shall be provided for the draining and venting of pressure equipment where necessary:
必要时，应为压力设备的排水和通风提供适当的方法：

— to avoid harmful effects such as water hammer, vacuum collapse, corrosion and uncontrolled chemical reactions. All stages of operation and testing, particularly pressure testing, shall be considered,
——为避免如水击作用，真空坍塌，腐蚀和不受控制的化学反应的有害影响。在所有操作和测试，特别是压力测试阶段应考虑该问题，

— to permit cleaning, inspection and maintenance in a safe manner.
——以安全方式进行清洁、检验和维护。

2.6. Corrosion or other chemical attack
2.6、腐蚀或其他化学侵蚀
Where necessary, adequate allowance or protection against corrosion or other chemical attack shall be provided, taking due account of the intended and reasonably foreseeable use.
考虑预期和可合理预见的使用，在必要时，应提供足够的余量或保护，防止腐蚀或其他化学侵蚀。

2.7. Wear
2.7、磨损
Where severe conditions of erosion or abrasion may arise, adequate measures shall be taken to:
当可能会出现严重的侵蚀或磨损时，应采取充分的措施：

— minimise that effect by appropriate design, e.g. additional material thickness, or by the use of liners or cladding materials,
——通过合适的设计以减少该影响，例如：额外的材料厚度，或通过使用衬垫或覆层材料，
— permit replacement of parts which are most affected,
——允许更换最严重受影响的零件，
— draw attention, in the instructions referred to in point 3.4, to measures necessary for continued safe use.
——需注意在 3.4 点提到的持续安全使用所需措施。

2.8. Assemblies
2.8、组合件
Assemblies shall be so designed that:
组合件应这样设计：

— the components to be assembled together are suitable and reliable for their duty,
——组装在一起的部件对于其使用条件是合适和可靠的，
— all the components are properly integrated and assembled in an appropriate manner.
——所有组件都以适当的方式正确地组成和组装。

2.9. Provisions for filling and discharge
2.9、充装和排空规定
Where appropriate, the pressure equipment shall be so designed and provided with accessories, or provision made for their fitting, as to ensure safe filling and discharge in particular with respect to risks such as:
可行时，压力设备应设计和提供附件或连接设备接口的设备，以确保安全充装和排空，特别考虑以下风险：

(a) on filling:
（a）充装：
— overfilling or overpressurisation having regard in particular to the filling ratio and to vapour pressure at the reference temperature,
——特别考虑到在参考温度时的填充比和蒸汽压力过高产生的过充或过压；
— instability of the pressure equipment;
——压力设备的不稳定性；

(b) on discharge: the uncontrolled release of the pressurised fluid;
（b）排空：加压流体不受控制的释放；

(c) on filling or discharge: unsafe connection and disconnection.
（c）充装和排空：不安全的连接和断开。

2.10. Protection against exceeding the allowable limits of pressure equipment
2.10、压力设备超出允许范围时的保护

Where, under reasonably foreseeable conditions, the allowable limits could be exceeded, the pressure equipment shall be fitted with, or provision made for the fitting of, suitable protective devices, unless the equipment is intended to be protected by other protective devices within an assembly.
在可合理预见压力设备会超出允许范围的情况下，必须配有合适的保护装置或连接设备接口的设备，除非该设备想用装在组合件内的其它保护装置进行保护。

The suitable device or combination of such devices shall be determined on the basis of the particular characteristics of the equipment or assembly.
合适的保护装置或组合体必须根据设备或组合件的特性来确定。

Suitable protective devices and combinations thereof comprise:
合适的保护装置或组合体包括：

(a) safety accessories as defined in point 4 of Article 2,
（a）在第 2 条第 4 点中定义的安全附件，

(b) where appropriate, adequate monitoring devices such as indicators and/or alarms which enable adequate action to be taken either automatically or manually to keep the pressure equipment within the allowable limits.
（b）如可行，足够的监测装置，如指示器和/或警报装置，可以通过自动或手动操作，采取足够措施保持压力设备在允许限制范围内。

2.11. Safety accessories
2.11、安全附件

2.11.1. Safety accessories shall:
2.11.1、安全附件应：
— be so designed and constructed as to be reliable and suitable for their intended duty and take into account the maintenance and testing requirements of the devices, where applicable,
——可靠且适合于其预期目的的设计和制造，可行时，考虑装置的维修和试验要求；

— be independent of other functions, unless their safety function cannot be affected by such other functions,
——独立于其他功能，除非安全功能不受其他功能的影响，

— comply with appropriate design principles in order to obtain suitable and reliable protection. These principles include, in particular, fail-safe modes, redundancy, diversity and self-diagnosis.
——符合合适的设计原则以获得合适且可靠的保护。这些原则特别包括故障-安全模式，冗余性、多样性和自我诊断。

2.11.2. Pressure limiting devices
2.11.2、限压装置
These devices shall be so designed that the pressure will not permanently exceed the maximum

allowable pressure PS; however a short duration pressure surge in keeping with the specifications laid down in point7.3 is allowable, where appropriate.
这些装置应被设计为压力不会永久超过最大允许压力，但可行时，根据 7.3 点要求，允许持续时间很短的压力波动。

2.11.3. Temperature monitoring devices
2.11.3、温度监控装置
These devices shall have an adequate response time on safety grounds, consistent with the measurement function.
这些设备具有测量功能的同时，出于安全考虑，应有足够的响应时间。

2.12. External fire
2.12、外部火灾
Where necessary, pressure equipment shall be so designed and, where appropriate, fitted with suitable accessories, or provision made for their fitting, to meet damage-limitation requirements in the event of external fire, having particular regard to its intended use.
在必要时，特别考虑到预期的使用，压力设备应设计，并在合适时配备适用的配件或连接设备接口的设备，以满足外部火灾事件有限损失的要求。

3. MANUFACTURING
3、制造
3.1. Manufacturing procedures
3.1、制造程序
The manufacturer shall ensure the competent execution of the provisions set out at the design stage by applying the appropriate techniques and relevant procedures, especially with a view to the aspects set out below.
制造商应通过适当的技术和相关的程序，确保在设计阶段所规定的执行能力，特别是对下面的几个方面。

3.1.1. Preparation of the component parts
3.1.1、零件制备
Preparation of the component parts (e.g. forming and chamfering) shall not give rise to defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the pressure equipment.
零件的制备（如成型或倒角）不得产生缺陷或裂纹或机械性能的变化，这可能会损害压力设备安全性。

3.1.2. Permanent joining
3.1.2、永久性连接
Permanent joints and adjacent zones shall be free of any surface or internal defects detrimental to the safety of the equipment.
永久性关节及相邻部分不得有任何不利于设备安全的表面或内部缺陷。

The properties of permanent joints shall meet the minimum properties specified for the

materials to be joined unless other relevant property values are specifically taken into account in the design calculations.
永久接头的性能应达到连接材料的最低性能，除非在设计计算中特别考虑了其他相关的属性。

For pressure equipment, permanent joining of components which contribute to the pressure resistance of equipment and components which are directly attached to them shall be carried out by suitably qualified personnel according to suitable operating procedures.
对于压力设备，有助于设备抵抗压力或直接连接到该设备的永久性连接组件，应由合适的合格人员按合适的操作程序完成。

For pressure equipment in categories II, III and IV, operating procedures and personnel shall be approved by a competent third party which, at the manufacturer's discretion, may be:
对于第 II 类、第 III 类和第 IV 类压力设备，经制造商慎重考虑，操作规程和人员须经有资质的第三方批准，他们可以是：

— a notified body,
——公告机构，
— a third-party organisation recognised by a Member State as provided for in Article 20.
——第 20 条规定的成员国认可第三方组织。

To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonised standards or equivalent examinations and tests or shall have them performed.
为了完成这些批准，第三方必须根据合适的协调标准要求，进行检验和测试，或等效检验和测试。

3.1.3. Non-destructive tests
3.1.3、无损试验
For pressure equipment, non-destructive tests of permanent joints shall be carried out by suitable qualified personnel. For pressure equipment in categories III and IV, the personnel shall be approved by a third-party organisation recognised by a Member State pursuant to Article 20.
对承压设备，应让合适的合格人员对永久性接头进行无损测试。对于第 III 类、第 IV 类压力设备，测试人员应经第 20 条成员国确认的第三方组织批准。

3.1.4. Heat treatment
3.1.4、热处理
Where there is a risk that the manufacturing process will change the material properties to an extent which would impair the safety of the pressure equipment, suitable heat treatment shall be applied at the appropriate stage of manufacture.
当存在制造过程会在某种程度上改变材料性能的风险，损害压力设备安全性时，应在适当的制造阶段使用合适的热处理。

3.1.5. Traceability
3.1.5、可追溯性

Suitable procedures shall be established and maintained for identifying the material making up the components of the equipment which contribute to pressure resistance by suitable means from receipt, through production, up to the final test of the manufactured pressure equipment.
应建立和保持合适的程序，从接收、到生产、再到制造的压力设备最终测试阶段，通过合适的方法，定位组成有助于抵御压力的设备的材料。

3.2. Final assessment
3.2、最终评定
Pressure equipment shall be subjected to final assessment as described below.
压力设备应进行如下所述的最终评定。

3.2.1. Final inspection
3.2.1、最终检验
Pressure equipment shall undergo a final inspection to assess visually and by examination of the accompanying documents compliance with the requirements of this Directive. Test carried out during manufacture may be taken into account. As far as is necessary on safety grounds, the final inspection shall be carried out internally and externally on every part of the equipment, where appropriate in the course of manufacture (e.g. where examination during the final inspection is no longer possible).
压力设备应进行最终检验，以进行目检评价并检查符合本指令要求的附属文件。可以考虑在制造过程中进行测试。就安全方面而言，如可以，最终检验应在制造阶段，对设备每一部分的内部和外部进行检查（例如，不可能在最终检验时检查的情况）。

3.2.2. Proof test
3.2.2、验收试验
Final assessment of pressure equipment shall include a test for the pressure containment aspect, which will normally take the form of a hydrostatic pressure test at a pressure at least equal, where appropriate, to the value laid down in point 7.4.
压力设备最终评定应包括压力密闭度方面的试验，一般来说是视情况，但至少与 7.4 点列出压力相等的情况下进行静态水压测试。

For category I series-produced pressure equipment, this test may be performed on a statistical basis.
对于 I 类压力设备系列产品，该测试可以在统计基础上进行。

Where the hydrostatic pressure test is harmful or impractical, other tests of a recognised value may be carried out. For tests other than the hydrostatic pressure test, additional measures, such as non-destructive tests or other methods of equivalent validity, shall be applied before those tests are carried out.
当静态水压测试是有害或不切实际时，可以进行其他认可的测试。对于除静态水压测试的额外试验，如非破坏性试验或其他等效试验，应在水压试验前进行。

3.2.3. Inspection of safety devices
3.2.3、安全装置检验

For assemblies, the final assessment shall also include a check of the safety devices intended to check full compliance with the requirements referred to in point 2.10.
对于组合件，最终评定还应包括对于安全装置的检查，目的在于检查是否完全满足第 2.10 点要求。

3.3. Marking and labelling
3.3、标记和标签
In addition to the CE marking referred to in Articles 18 and 19 and the information to be provided in accordance with Article 6(6) and Article 8(3), the following information shall be provided:
除了在第 18 条和第 19 条所提到的 CE 标识及根据第 6 条第（6）款和第 8 条第（3）款需要提供的资料，还应提供下列资料：

(a) for all pressure equipment:
（a）对于所有压力设备：
— the year of manufacture,
——制造年份，
— identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number,
——根据压力设备性质，如型号、系列或批次标识和序列号，对其进行识别
— essential maximum/minimum allowable limits.
——基本最大/最小允许（压力）限制。

(b) depending on the type of pressure equipment, further information necessary for safe installation, operation or use and, where applicable, maintenance and periodic inspection such as:
（b）根据压力设备的类型，为安全安装、操作或使用，以及维护和定期检查（如适用）所需的进一步资料，如：
— the volume V of the pressure equipment in L,
——压力设备的体积 V，用 L 表示
— the nominal size for piping DN,
——管道公称直径 DN，
— the test pressure PT applied in bar and date,
——测试压力 PT，用 Bar 表示和测试日期，
— safety device set pressure in bar,
——安全装置设置压力，用 Bar 表示，
— output of the pressure equipment in kW,
——压力设备的输出功率，用 kW 表示，
— supply voltage in V (volts),
——电源电压，用 V（伏特）表示，
— intended use,
——预期用途，
— filling ratio kg/L,
——填充比，用 kg/L 表示，
— maximum filling mass in kg,

——最大填充质量，用 kg 表示，
— tare mass in kg,
——自重，用 kg 表示，
— the fluid group.
——流体组别。

(c) where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.
（c）在必要时，固定在压力设备上的警告，注意根据经验显示可能会产生的误用。

The information referred to in points (a), (b) and (c) shall be given on the pressure equipment or on a dataplate firmly attached to it, with the following exceptions:
点（a）、（b）和（c）提到的信息应在压力设备或固定在设备上的铭牌体现，除了以下例外：

— where applicable, appropriate documentation may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly,
——可酌情使用适当文件，避免用于相同组合件的个别零件（如管道组件）重复标记，

— where the pressure equipment is too small, e.g. accessories, this information may be given on a label attached to that pressure equipment,
——当压力设备（如附件）太小时，该信息可在系于承压设备的标签上说明，

— labelling or other adequate means may be used for the mass to be filled and the warnings referred to in point(c), provided it remains legible for the appropriate period of time.
——若在适当的时间内保持清晰，标签或其它恰当的方法可用于充装量和(c)段所指的警告。

3.4. Operating instructions
3.4、操作说明
(a) When pressure equipment is made available on the market, it shall be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to:
（a）当压力设备在市场流通时，应附有用户说明书及相关文件，包含以下所有相关必要安全信息：
— mounting including assembling of different pieces of pressure equipment,
——安装，包括不同压力设备的组装，
— putting into service,
——投入运行，
— use,
——使用，
— maintenance including checks by the user.
——维护，包括用户检查。

(b) Instructions shall cover information affixed to the pressure equipment in accordance with point 3.3, with the exception of serial identification, and shall be accompanied, where appropriate, by the technical documents, drawings and diagrams necessary for a full

understanding of these instructions.
（b）说明应涵盖第 3.3 点所述的附在压力设备上，除了序列号以外的信息，并应酌情附上为充分理解这些说明所需的技术文件、图纸和图表。

(c) If appropriate, these instructions shall also refer to risks arising from misuse in accordance with point 1.3 and particular features of the design in accordance with point 2.2.3.
（c）如果适当的话，这些说明也应提及由于点 1.3 所述的误用及点 2.2.3 所述的设计特点产生的风险。

4. MATERIALS
4、材料
Materials used for the manufacture of pressure equipment shall be suitable for such application during the scheduled lifetime unless replacement is foreseen.
用于制造压力设备的材料应在预定寿命内适合用于该情况，除非有可预见的更换。

Welding consumables and other joining materials need to fulfil only the relevant requirements of points 4.1, 4.2(a) and the first paragraph of point 4.3, in an appropriate way, both individually and in a joined structure.
无论是单独还是连接结构，焊接耗材和其他连接材料只需以适当的方式，满足点 4.1，4.2（a）和 4.3 第一段的相关要求。

4.1. Materials for pressurised parts shall:
4.1、受压部件材料应：
(a) have appropriate properties for all operating conditions which are reasonably foreseeable and for all test conditions, and in particular they should be sufficiently ductile and tough. Where appropriate, the characteristics of the materials shall comply with the requirements of point 7.5. Moreover, due care should be exercised in particular in selecting materials in order to prevent brittle-type fracture where necessary; where for specific reasons brittle material has to be used appropriate measures shall be taken;
（a）具有合适的满足所有可合理预见的操作情况和所有测试条件的性能，特别是应具有足够的延展性和韧性。若可以，材料性能应符合第 7.5 点的要求。此外，在选择材料时应必需特别注意，防止脆性断裂；当有特殊原因必需使用脆性材料时，应采取适当措施；

(b) be sufficiently chemically resistant to the fluid contained in the pressure equipment; the chemical and physical properties necessary for operational safety shall not be significantly affected within the scheduled lifetime of the equipment;
（b）对压力设备中所含流体有足够的耐化学腐蚀性；为操作安全所必需的化学和物理性能在设备预期寿命内不会有显著变化；

(c) not be significantly affected by ageing;
（c）不受显著的老化影响；

(d) be suitable for the intended processing procedures;
（d）适用于预期处理程序；

(e) be selected in order to avoid significant undesirable effects when the various materials are put together.
（e）（慎重）选择，避免各种物料放在一起产生显着不良影响。

4.2. The pressure equipment manufacturer shall:
4.2、压力设备制造商应：
(a) define in an appropriate manner the values necessary for the design calculations referred to in point 2.2.3 and the essential characteristics of the materials and their treatment referred to in point 4.1;
（a）以适当方式定义在 2.2.3 提到的设计计算所需的数值和在 4.1 中提到的材料基本性能和处理方式；

(b) provide in his technical documentation elements relating to compliance with the materials specifications of this Directive in one of the following forms:
（b）在技术文件中提供相关符合本指令材料规范的资料，用以下方式之一表示：

— by using materials which comply with harmonised standards,
——使用符合协调标准的材料，
— by using materials covered by a European approval of pressure equipment materials in accordance with Article 15,
——按第 15 条欧洲批准压力设备材料所覆盖的材料，
— by a particular material appraisal;
——通过特定评估的材料；

(c) for pressure equipment in categories III and IV, a specific assessment of the particular material appraisal shall be performed by the notified body in charge of conformity assessment procedures for the pressure equipment.
（c）对于第 III、第 IV 类承压设备，特定材料评价的具体评估应由公告机构在对压力设备合格评定时进行。

4.3. The equipment manufacturer shall take appropriate measures to ensure that the material used conforms with the required specification. In particular, documentation prepared by the material manufacturer affirming compliance with a specification shall be obtained for all materials.
4.3、设备制造商应采取适当的措施，以确保所使用的材料符合规范要求。尤其是，所有材料应获得材料制造商提供的证明符合规范的文件。

For the main pressure-bearing parts of equipment in categories II, III and IV, this shall take the form of a certificate of specific product control.
对于第 II、第 III 和第 IV 类设备的主要承压部件，应采用特定产品控制证书的方式进行。

Where a material manufacturer has an appropriate quality-assurance system, certified by a competent body established within the Union and having undergone a specific assessment for

materials, certificates issued by the manufacturer are presumed to certify conformity with the relevant requirements of this point.
当材料制造商有合适的、由建立在欧盟且有能力的机构认证的质量保证体系，并且材料经过特定评定，制造商颁发的证书被推定符合这一点的相关要求。

SPECIFIC PRESSURE EQUIPMENT REQUIREMENTS
特殊压力设备的要求

In addition to the applicable requirements of points 1 to 4, the following requirements apply to the pressure equipment covered by points 5 and 6.
除了第 1 点至 4 点的要求外，以下要求适用于第 5 和第 6 点涵盖的压力设备。

5. FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH A RISK OF OVERHEATING AS REFERRED TO IN ARTICLE 4(1)
5、用火或以其他方式加热的压力设备有在第 4 条第（1）款提到的过热风险

This pressure equipment includes:
该压力设备包括：
— steam and hot-water generators as referred to in Article 4(1)(b), such as fired steam and hot-water boilers, superheaters and reheaters, waste-heat boilers, waste incineration boilers, electrode or immersion-type electrically heated boilers, pressure cookers, together with their accessories and where applicable their systems for treatment of feedwater and for fuel supply,
——第 4 条第（1）款第（b）条提到的蒸汽和热水产生器，如受火蒸汽和热水锅炉、过热器和再热器、余热锅炉、垃圾焚烧锅炉、电极或浸入式电加热锅炉、压力锅，连同他们的配件和处理给水及燃料供应系统（如适用），

— process-heating equipment for other than steam and hot water generation falling under Article 4(1)(a), such as heaters for chemical and other similar processes and pressurised food-processing equipment.
——第 4 条第（1）款第（a）条提到的非蒸汽和热水锅炉以外的工艺加热设备，如化学和类似工艺和食品加工的承压设备。

This pressure equipment shall be calculated, designed and constructed so as to avoid or minimise risks of a significant loss of containment from overheating. In particular it shall be ensured, where applicable, that:
计算，设计和建造压力设备时，应避免或尽量减少过热导致密闭性严重损失的风险。特别是应酌情确保：

(a) appropriate means of protection are provided to restrict operating parameters such as heat input, heat take- off and, where applicable, fluid level so as to avoid any risk of local and general overheating;
（a）应提供适当的保护装置，以控制运行参数如热输入、热放出以及在合适的情况下，流体的状态，以便避免任何整体或局部过热的风险；

(b) sampling points are provided where required to allow evaluation of the properties of the fluid so as to avoid risks related to deposits and/or corrosion;
（b）为避免有关沉淀物或腐蚀风险而要求评定流体的性能时，在需要时提供取样位置；

(c) adequate provisions are made to eliminate risks of damage from deposits;
（c）为了消除沉积物的损害风险，采取充分预防措施；

(d) means of safe removal of residual heat after shutdown are provided;
（d）提供安全去除关闭后余热的方法；

(e) steps are taken to avoid a dangerous accumulation of ignitable mixtures of combustible substances and air, or flame blowback.
（e）采取措施，以避免燃烧物质和空气的可燃混合物的危险聚集以及回火。

6. PIPING AS REFERRED TO IN ARTICLE 4(1)(c)
6、第 4 条第（1）款第（c）点所指的管道

Design and construction shall ensure:
设计和施工应确保：

(a) that the risk of overstressing from inadmissible free movement or excessive forces being produced, e.g. on flanges, connections, bellows or hoses, is adequately controlled by means such as support, constraint, anchoring, alignment and pre-tension;
（a）通过支撑，约束，锚定、校正和预紧的方式，充分控制如在法兰、连接、波纹管或软管处，由于不允许自由活动或过大力所产生的超负荷风险；

(b) that where there is a possibility of condensation occurring inside pipes for gaseous fluids, means are provided for drainage and removal of deposits from low areas to avoid damage from water hammer or corrosion;
（b）气态流体内管发生冷凝的可能，为避免水击或腐蚀导致的损害，可从低处设置除水装置排放或去除沉积物；

(c) that due consideration is given to the potential damage from turbulence and formation of vortices; the relevant parts of point 2.7 are applicable;
（c）考虑到湍流和形成涡流的潜在风险；可采用 点 2.7 的相关部分；

(d) that due consideration is given to the risk of fatigue due to vibrations in pipes;
（d）考虑到管内振动而引起的疲劳风险；

(e) that, where fluids of Group 1 are contained in the piping, appropriate means are provided to isolate 'take-off' pipes the size of which represents a significant risk;
（e）如果管道输运第 1 组的流体，考虑在有很大风险的部位设置恰当装置以隔离水管；

(f) that the risk of inadvertent discharge is minimised; the take-off points shall be clearly marked on the permanent side, indicating the fluid contained;
（f）将疏忽排放的风险降低到最小；必须在固定一侧清楚标注排放位置，并表明所含流体；

(g) that the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection or repair.
（g）地下管道的位置和路线至少记录在技术文件中，方便安全维护、检查或维修。

7. SPECIFIC QUANTITATIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT
7、特定压力设备的具体定量要求

The following provisions apply as a general rule. However, where they are not applied, including in cases where materials are not specifically referred to and no harmonised standards are applied, the manufacturer shall demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.
以下规定作为一般规则。然而，当材料没有被专门提到或没有使用协调标准时，不适用该规则，制造商应表明已采取适当的措施，以达到整体等同的安全水平。

The provisions laid down in this section supplement the essential safety requirements of points 1 to 6 for the pressure equipment to which they apply.
本节规定为适用的压力设备制定，作为第 1 点至第 6 点的基本安全要求的补充。

7.1. Allowable stresses
7.1、允许应力
7.1.1. Symbols
7.1.1、符号

$R_{e/t}$, yield limit, indicates the value at the calculation temperature of:
$R_{e/t}$ ，表示在计算温度下的屈服极限值：
— the upper flow limit for a material presenting upper and lower flow limits,
——材料出现上下屈服限时的上屈服指，
— the 1,0 % proof strength of austenitic steel and non-alloyed aluminium,
——对奥氏体钢和非合金铝，1.0 %屈服强度，

— the 0,2 % proof strength in other cases.
——其他情况，0.2%的屈服强度。

$R_{m/20}$ indicates the minimum value of the ultimate tensile strength at 20 °C.
$R_{m/20}$ 表示在 20℃时抗拉强度的最小值。

$R_{m/t}$ designates the ultimate tensile strength at the calculation temperature.
$R_{m/t}$ 指在计算温度时的抗拉强度。

7.1.2. The permissible general membrane stress for predominantly static loads and for temperatures outside the range in which creep is significant shall not exceed the smaller of the following values, according to the material used:
7.1.2、对于主要静载荷和对于温度在明显蠕变范围外的情况，根据所用材料，一般薄膜应力不得超过下列值的较小值：

— in the case of ferritic steel including normalised (normalised rolled) steel and excluding fine-grained steel and specially heat-treated steel, 2 / 3 of $R_{e/t}$ and 5 / 12 of $R_{m/20}$,
——针对铁素体钢，包括正火（正火轧制）钢，不包括细化晶粒钢和特殊热处理钢，2 / 3 的 $R_{e/t}$ 或 5 / 12 的 $R_{m/20}$，

— in the case of austenitic steel:
——针对奥氏体钢：
— if its elongation after rupture exceeds 30 %, 2 / 3 of $R_{e/t}$
——如果断裂伸长率超过 30%，2 / 3 的 $R_{e/t}$
— or, alternatively, and if its elongation after rupture exceeds 35 %, 5 / 6 of $R_{e/t}$ and 1 / 3 of $R_{m/t}$,
——或者，如果其断裂伸长率超过 35%，5 / 6 的 $R_{e/t}$ 或 3 / 1 的 $R_{m/t}$，

— in the case of non-alloy or low-alloy cast steel, 10 / 19 of $R_{e/t}$ and 1 / 3 of $R_{m/20}$,
——针对非合金或低合金钢，10 / 19 的 $R_{e/t}$ 或 1 / 3 的 $R_{m/20}$，

— in the case of aluminium, 2 / 3 of $R_{e/t}$,
——针对铝，2 / 3 的 $R_{e/t}$，

— in the case of aluminium alloys excluding precipitation hardening alloys 2 / 3 of $R_{e/t}$ and 5 / 12 of $R_{m/20}$.
——针对不包括固溶硬化合金的铝合金， 2/ 3 的 $R_{e/t}$ 或 5 / 12 的 $R_{m/20}$。

7.2. Joint coefficients
7.2、接头系数
For welded joints, the joint coefficient shall not exceed the following values:
对于焊接接头，接头系数不得超过下列值：

— for equipment subject to destructive and non-destructive tests which confirm that the whole

series of joints show no significant defects: 1,
——设备属于破坏和非破坏性测试，确认整个系列的接头没有显著缺陷：1，
— for equipment subject to random non-destructive testing: 0,85,
——设备属于随机无损检测：0,85，
— for equipment not subject to non-destructive testing other than visual inspection: 0,7.
——设备不属于无损检测或目检：0,7。

If necessary, the type of stress and the mechanical and technological properties of the joint shall also be taken into account.
如有必要，应考虑应力的类型和接头的机械与工艺性能。

7.3. Pressure limiting devices, particularly for pressure vessels
7.3、压力限制装置，特别是压力容器

The momentary pressure surge referred to in point 2.11.2 shall be kept to 10 % of the maximum allowable pressure.
第 2.11.2 点提到的瞬间压力骤增，应在最大允许压力 10%之内。

7.4. Hydrostatic test pressure
7.4、静态水压试验压力
For pressure vessels, the hydrostatic test pressure referred to in point 3.2.2 shall be no less than either of the following:
第 3.2.2 点提到的压力容器静态水压试验压力应不小于以下任一：

— that corresponding to the maximum loading to which the pressure equipment may be subject in service taking into account its maximum allowable pressure and its maximum allowable temperature, multiplied by the coefficient 1,25,
——对应压力设备在使用中可能受到的最大载荷，考虑其最大允许压力和最大允许温度，乘以系数 1,25，

— the maximum allowable pressure multiplied by the coefficient 1,43, whichever is the greater.
——最大允许压力乘以系数 1,43，以较大者为准。

7.5. Material characteristics
7.5、材料性能

Unless other values are required in accordance with other criteria that shall be taken into account, a steel is considered as sufficiently ductile to satisfy point 4.1(a) if, in a tensile test carried out by a standard procedure, its elongation after rupture is no less than 14 % and its bending rupture energy measured on an ISO V test-piece is no less than 27 J, at a temperature not greater than 20 °C but not higher than the lowest scheduled operating temperature.
除非有其他应考虑的特性需要其他数值，如果在标准步骤进行的拉伸测试中，断后延伸率大于 14%，且在温度不大于 20℃、不高于最低设定操作温度的条件下，按 ISO 标准 V 型试样测弯曲断裂能不低于 27 J 时，可认为钢有足够的延展性来满足 4.1(a)的要求。

ANNEX II
附录二
CONFORMITY ASSESSMENT TABLES
合格评定表

1. The references in the tables to categories of modules are the following:
1、在表中的引用类别模式如下：

I	=	Module A 模式 A
II	=	Modules A2, D1, E1 模式 A2、D1、E1
III	=	Modules B (design type) + D, B (design type) + F, B (production type) + E, B (production type) + C2, H 模式 B（设计型）+ D，B（设计型）+ F、B（生产型）+ E、B（生产型）+ C2，H
IV	=	Modules B (production type) + D, B (production type) + F, G, H1 模式 B（生产型）+ D，B（生产型）+ F，G，H

2. The safety accessories defined in point 4 of Article 2, and referred to in Article 4(1)(d), are classified in category IV.
2、在第 2 条第 4 点中定义，以及第 4 条第（1）款第（d）点中所指的的安全附件，被分为第 IV 类。

However, by way of exception, safety accessories manufactured for specific equipment may be classified in the same category as the equipment they protect.
然而，通过例外方式，为特定设备制造的安全附件可分为他们保护设备的同一类。

3. The pressure accessories defined in point 5 of Article 2, and referred to in Article 4(1)(d), are classified on the basis of:
3、在第 2 条第 5 点定义，第 4 条第（1）款第（d）点中所指的的压力附件，根据以下分类：

— their maximum allowable pressure PS,
——最大允许压力 PS，
— their volume V or their nominal size DN, as appropriate,
——体积 V 或合适的公称直径 DN，
— the group of fluids for which they are intended.
——设定的液体组别。

The appropriate table for vessels or piping is to be used to determine the conformity assessment category.
合适的容器或管道表是用来确定合格评定类别。

Where both the volume and the nominal size are considered appropriate in the second indent of the first subparagraph, the pressure accessory shall be classified in the highest category.
当容积和公称直径都被认为适合第 1 段第 2 节时，压力附件应被划分为最高类别。

4. The demarcation lines in the following conformity assessment tables indicate the upper limit for each category.

4、下面的合格评定表中的划分线表示每个类别的上限。

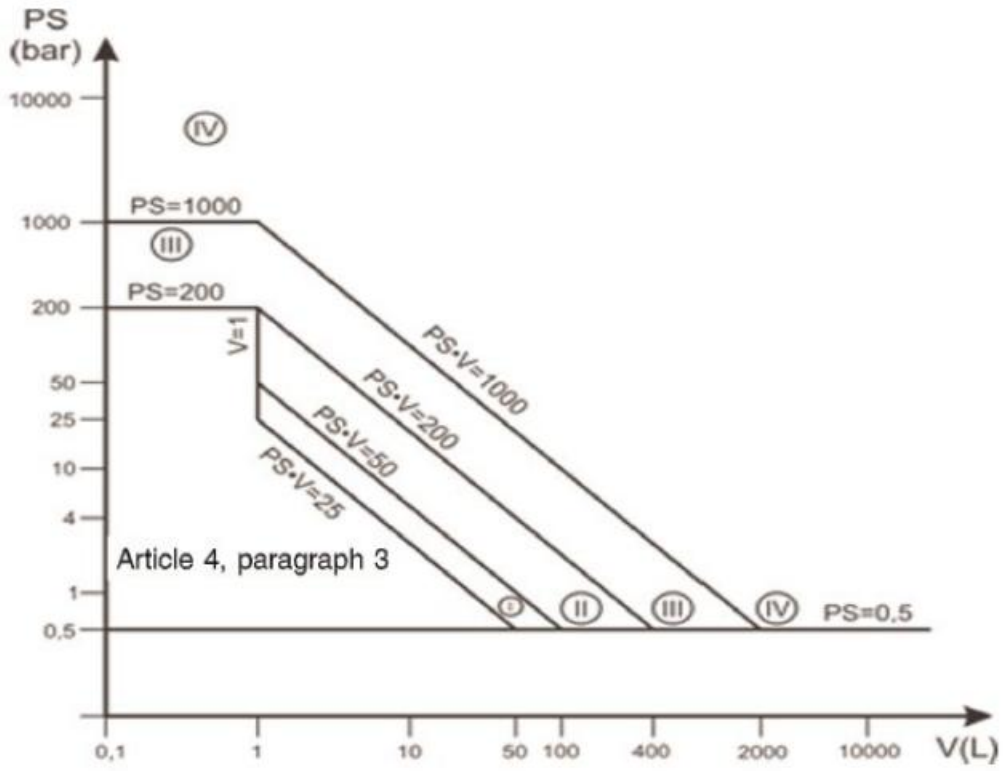

Table 1

表 1

Vessels referred to in Article 4(1)(a)(i), first indent

第 4 条第(1)(a)(i)节第 1 段所指的容器

Exceptionally, vessels intended to contain an unstable gas and falling within categories I or II on the basis of table 1 shall be classified in category III.

例外，容器预设含有不稳定气体，并在表 1 基础上划分为类别 I 或 II 的，应被划分为类别 III。

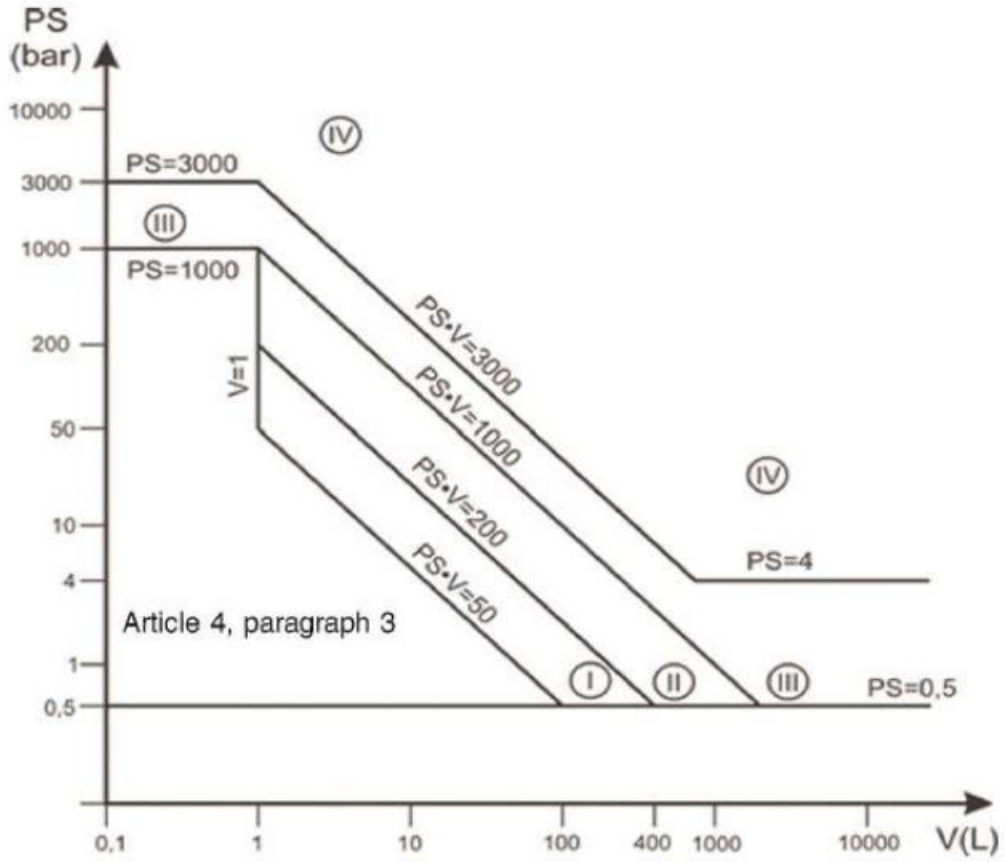

Table 2

表 2

Vessels referred to in Article 4(1)(a)(i), second indent

第 4 条第(1)(a)(i)节第 2 段所指的容器

Exceptionally, portable extinguishers and bottles for breathing equipment shall be classified at least in category III.

例外，便携式灭火器和用于呼吸设备瓶体应至少划分在类别 III 中。

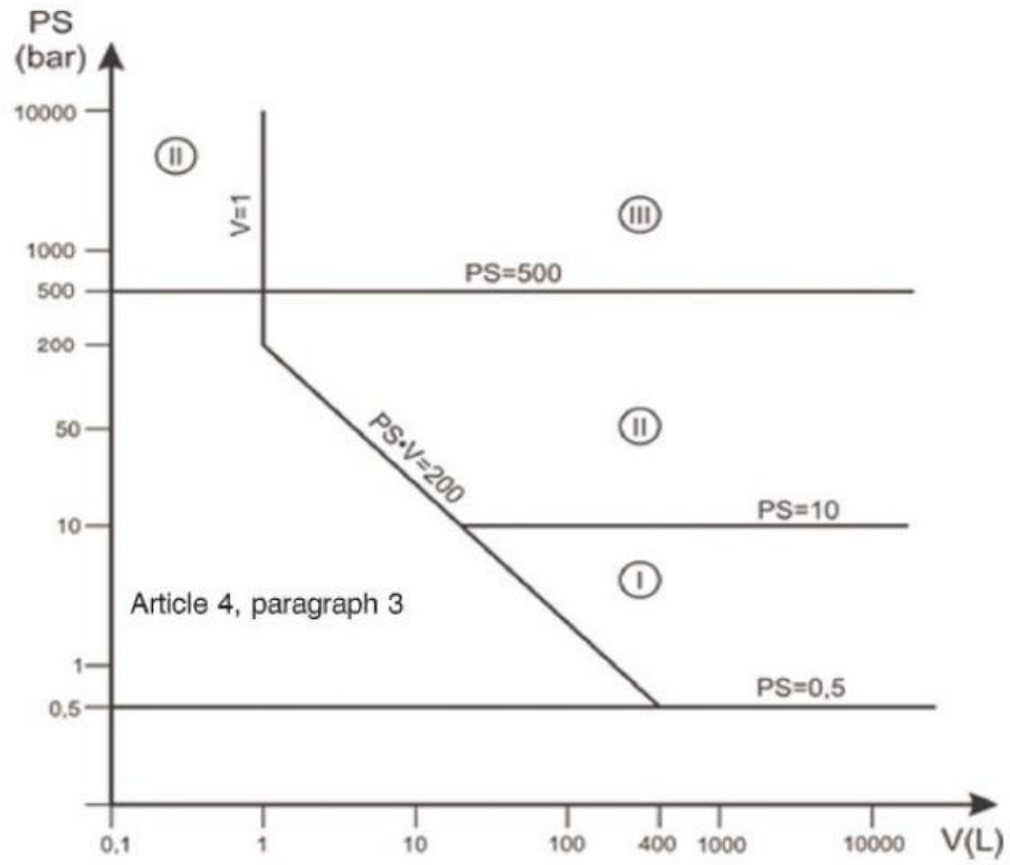

Table 3

表 3

Vessels referred to in Article 4(1)(a)(ii), first indent

第 4 条第(1)(a)(ii)节第 1 段所指的容器

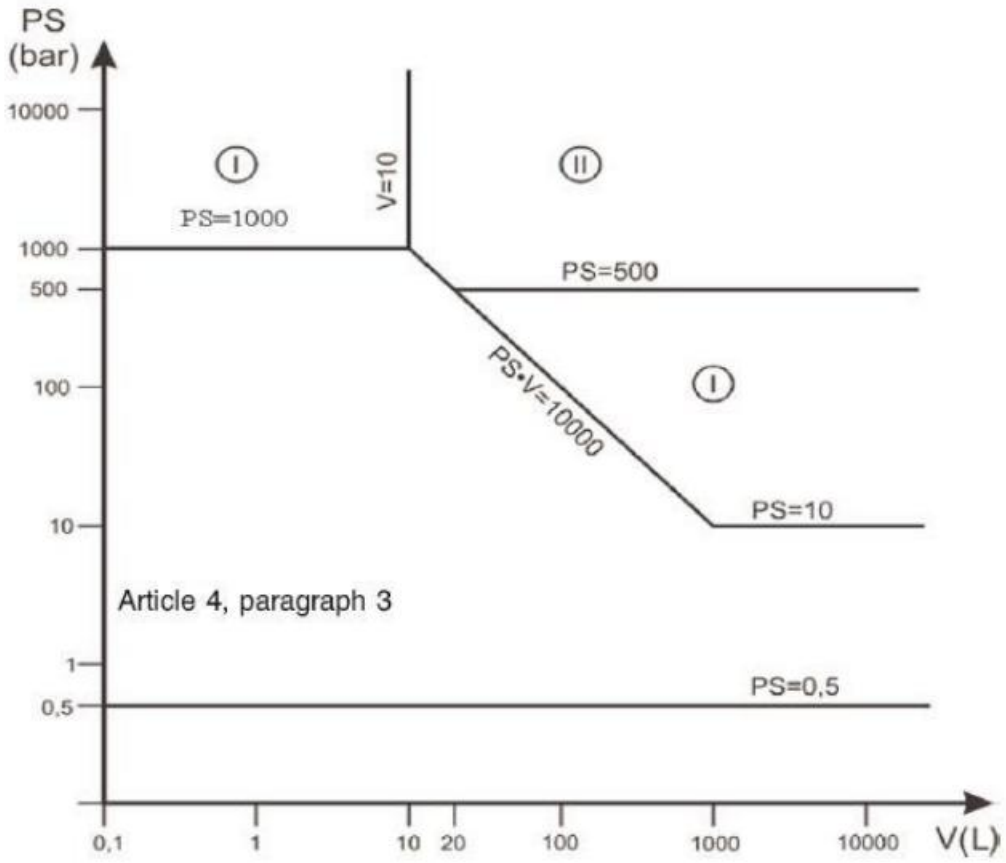

Table 4

表 4

Vessels referred to in Article 4(1)(a)(ii), second indent

第 4 条第(1)(a)(ii)节第 2 段所指的容器

Exceptionally, assemblies intended for generating warm water as referred to in the second subparagraph of Article 4(2), shall be subject either to an EU-type examination (Module B — design type) with respect to their conformity with the essential requirements referred to in points 2.10, 2.11, 3.4, 5(a) and 5(d) of Annex I, or to full quality assurance (Module H).

例外，第 4 条第(2)款第 2 段所指的用于产生热水的压力组合件应符合附录 I 第 2.10、2.11、3.4、5(a)和 5(d)节基本安全要求的 EU 型式检验（模式 B—设计型），或全面质量保证（模式 H）。

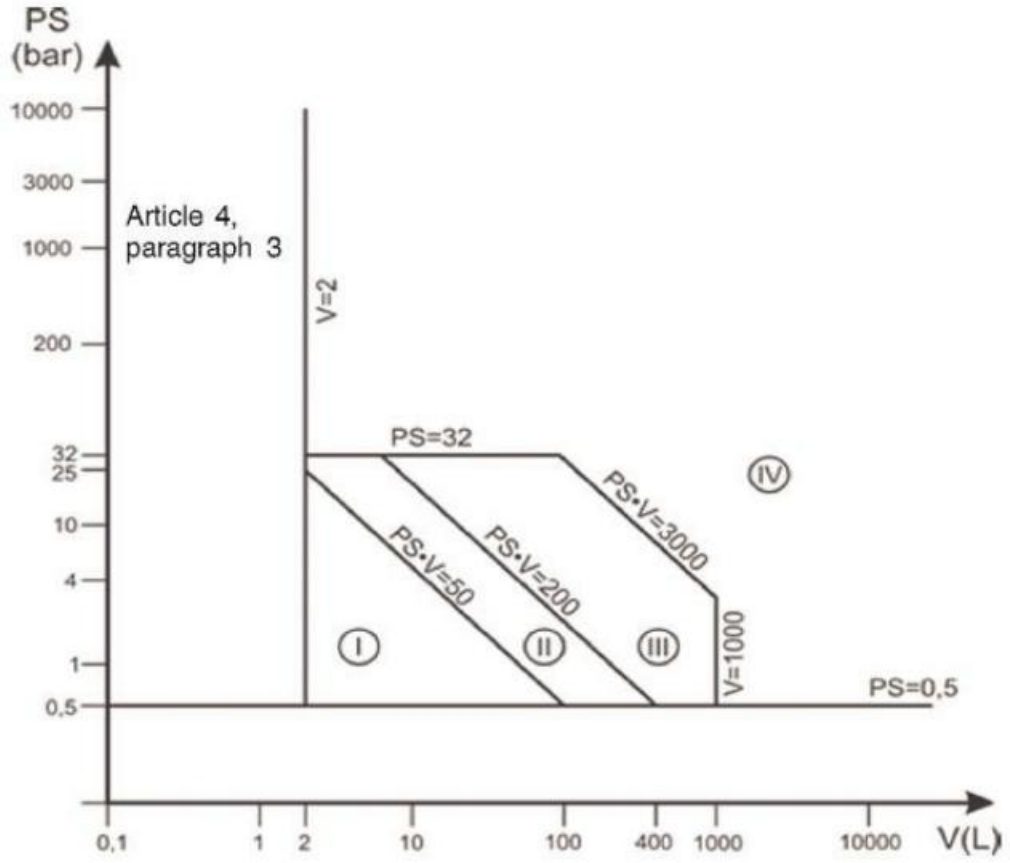

Table 5

表 5

Pressure equipment referred to in Article 4(1)(b)

第 4 条第(1)(b)条所指的压力设备

Exceptionally, the design of pressure-cookers shall be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

例外，压力锅的设计合格评定程序应属于至少相当于类别 III 模式中的一个。

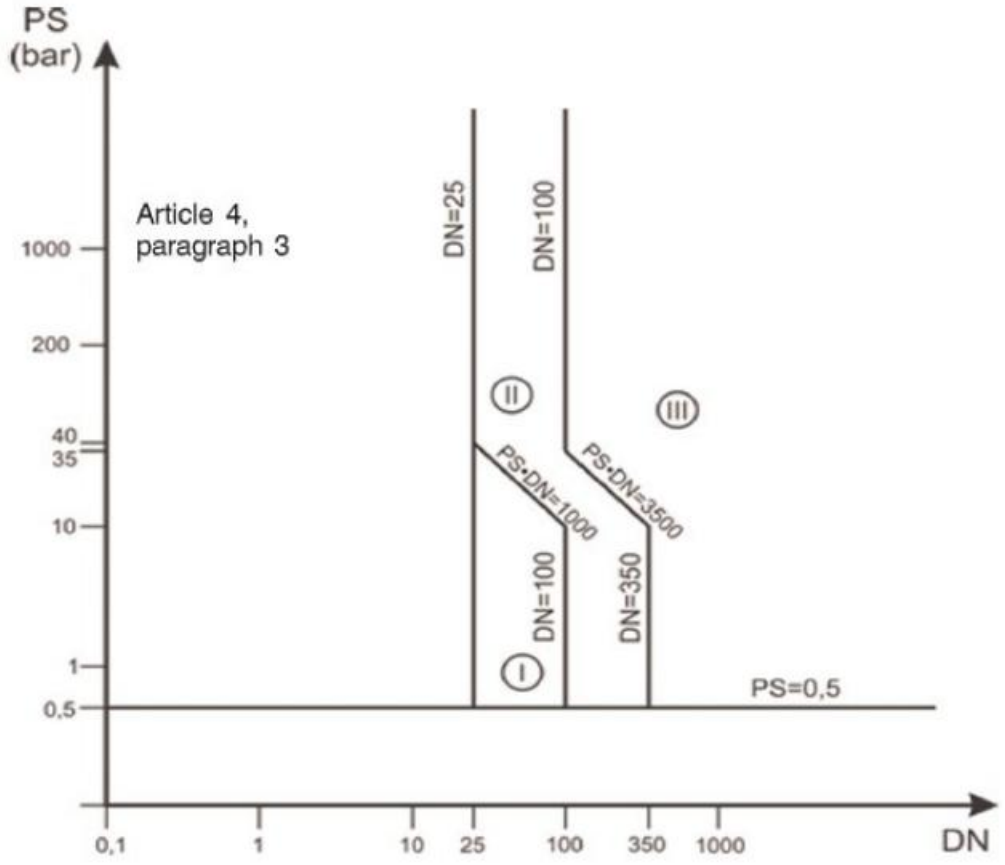

Table 6

表 6

Piping referred to in Article 4(1)(c)(i), first indent

第 4 条第(1)(c)(i)节第 1 段所指的管道

Exceptionally, piping intended for unstable gases and falling within categories I or II on the basis of Table 6 shall be classified in category III.

例外，管道预设含有不稳定气体，并在表 6 基础上划分为类别 I 或 II 的，应被划分为类别 III。

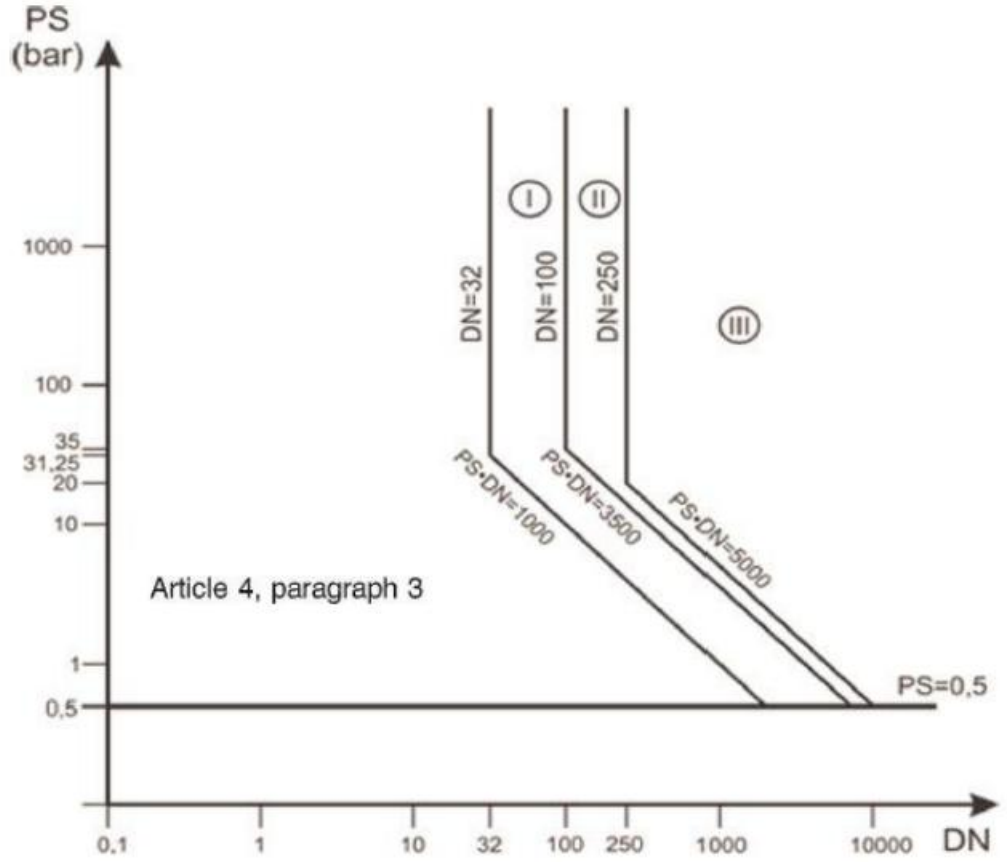

Table 7

表 7

Piping referred to in Article 4(1)(c)(i), second indent

第 4 条第(1)(c)(i)节第 2 段所指的管道

Exceptionally, all piping containing fluids at a temperature greater than 350 °C and falling within category II on the basis of Table 7 shall be classified in category III.

例外，所有温度大于 350° C，并在表 7 类别 II 中的管道应划分为类别 III。

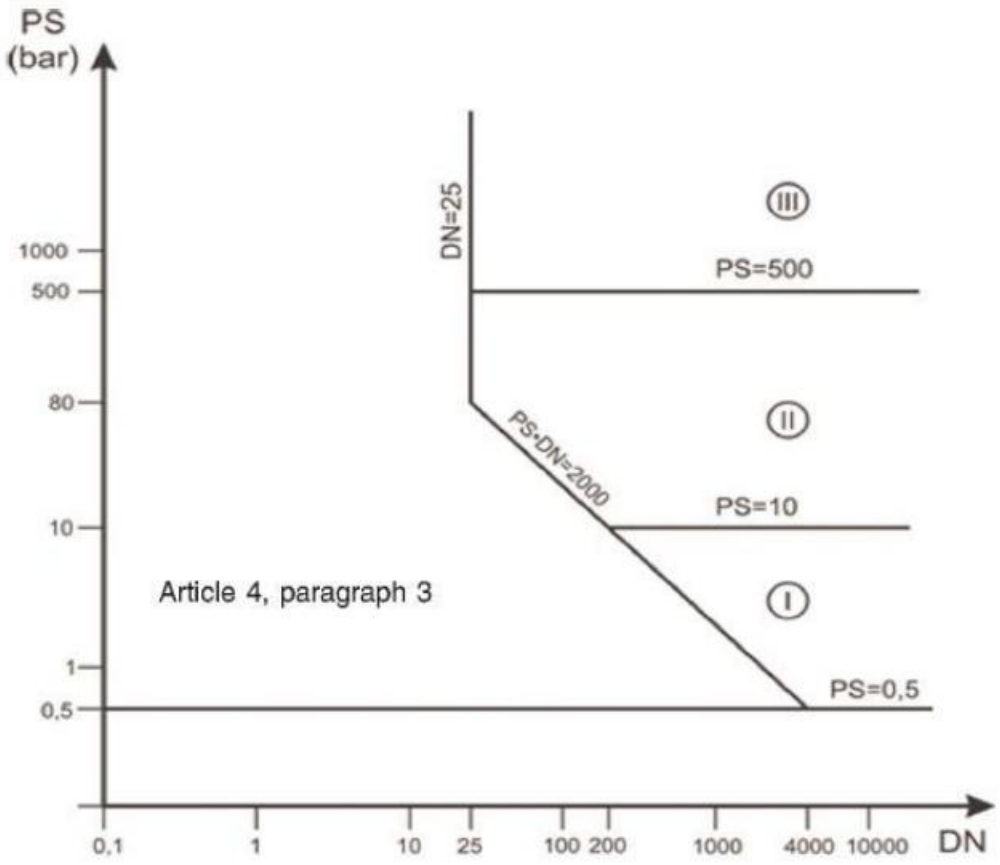

Table 8

表 8

Piping referred to in Article 4(1)(c)(ii), first indent

第 4 条第(1)(c)(ii)节第 1 段所指的管道

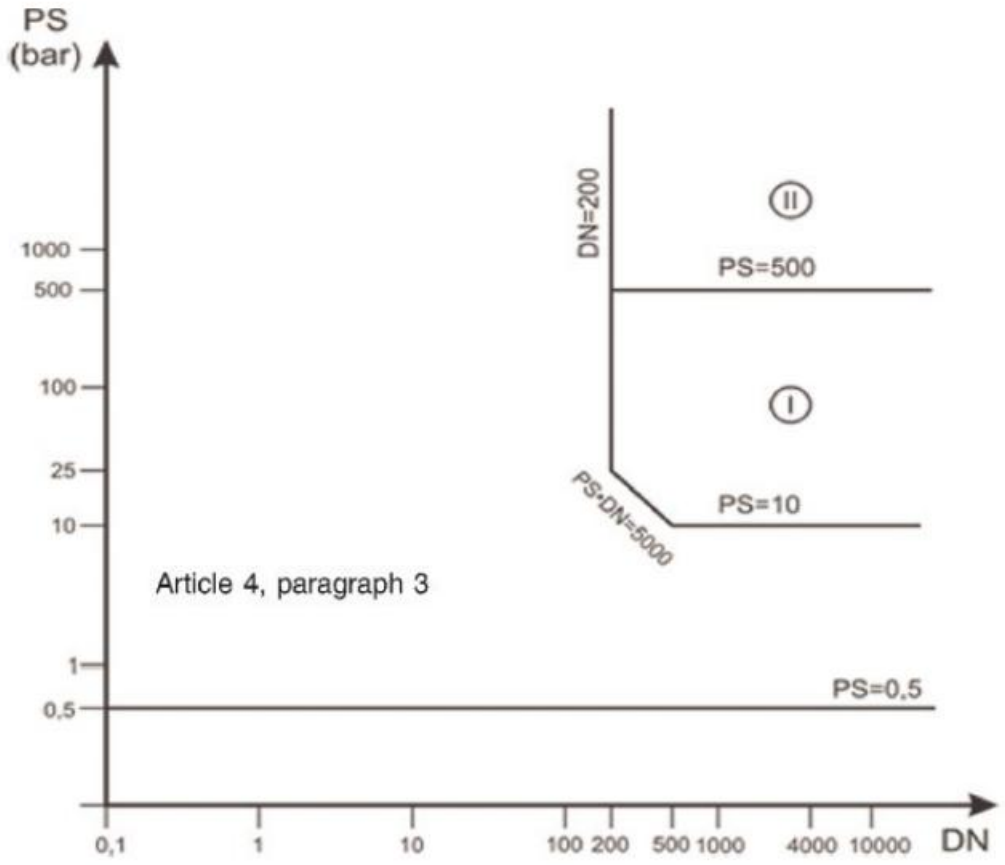

Table 9

表 9

Piping referred to in Article 4(1)(c)(ii), second indentE

第 4 条第(1)(c)(ii)节第 2 段所指的管道

ANNEX III
附录三
CONFORMITY ASSESSMENT PROCEDURES
合格评定程序

The obligations arising from the provisions on pressure equipment in this Annex also apply to assemblies.
本附录对压力设备的规定产生的义务也适用于组合件。

1. MODULE A: (INTERNAL PRODUCTION CONTROL)
1、模式 A：（内部生产控制）

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive.
1、内部生产控制是制造商满足第 2、3 和 4 点的义务，并确保和宣布了评定的压力设备满足本指令要求唯一责任的合格评定程序。

2. Technical documentation
2、技术文件

The manufacturer shall establish the technical documentation. The technical documentation shall make it possible to assess the conformity of the pressure equipment to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall, wherever applicable, contain at least the following elements:
制造商应制定技术文件。技术文件应可以评定压力设备符合相关要求，并应包括充分的风险分析和评定。技术文件应指定适用的要求，并涵盖评定相关的压力设备设计、制造和操作。技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,
——为理解图纸和图表及操作压力设备所需的描述和解释，
— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and a description of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，

— results of design calculations made, examinations carried out, etc.,

——设计计算的结果，进行的验证等，

— test reports.

——测试报告。

3. Manufacturing

3、制造

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in point 2 and with the requirements of this Directive.

制造商应采取一切必要的措施，确保所制造的压力设备在制造过程及其监控过程中满足第 2 点提到的技术文件及本指令的要求。

4. CE marking and EU declaration of conformity

4、CE 标识与欧盟符合性声明

4.1. The manufacturer shall affix the CE marking to each individual pressure equipment that satisfies the applicable requirements of this Directive.

4.1、制造商应在满足本指令适用要求的每一个压力设备上贴上 CE 标识。

4.2. The manufacturer shall draw up a written EU declaration of conformity for the pressure equipment model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.

4.2、在压力设备投放市场后，制造商应在国内权威机构处理后，为压力设备类型制定一份书面的欧盟符合性声明并与技术文件一同保存 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

应照相关机构要求，提供欧盟符合性声明副本。

5. Authorised representative

5、授权代表

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

第 4 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

2. MODULE A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS

2、模式 A2：内部生产控制+随机间隔的监管压力设备检查

1. Internal production control plus supervised pressure equipment checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive.
1、内部生产控制+随机间隔的监管压力设备检查是合格评定过程中，制造商满足第 2、3、4 和 5 点的义务，并确保和宣布了评定的压力设备满足本指令要求唯一责任的合格评定程序。

2. Technical documentation
2、技术文件
The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall contain, wherever applicable, at least the following elements:
制造商应建立技术文件。该技术文件应可以评定压力设备符合相关要求，并应包括充分的风险分析和评定。技术文件应指定适用的要求，并涵盖评定相关的压力设备的设计、制造和操作。技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
——为理解图纸和图表及操作压力设备所需的描述和解释，
— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，
— results of design calculations made, examinations carried out, etc., and
——设计计算的结果，进行的验证等，
— test reports.
——测试报告。

3. Manufacturing
3、制造
The manufacturer shall take all measures necessary so that the manufacturing process and its

monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to it.
制造商应采取一切必要的措施，确保所制造的压力设备在制造过程及其监控，来满足第 2 点提到的技术文件及本指令的要求。

4. Final assessment and pressure equipment checks
4、最终评定和压力设备检查
The manufacturer shall perform a final assessment of the pressure equipment, monitored by means of unexpected visits by a notified body chosen by the manufacturer.
制造商应对压力设备进行最终评定，通过由制造商选择的公告机构以突然拜访的方式进行监控。

The notified body shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the pressure equipment, taking into account, inter alia, the technological complexity of the pressure equipment and the quantity of production.
公告机构应进行产品检查，或者在确定的时间间隔内进行产品检验
机构，以验证压力设备内部检查的质量，考虑到，除其他外，
压力设备的技术复杂度与生产量。

During its unexpected visits, the notified body shall:
在突然拜访期间，公告机构应：

— establish that the manufacturer actually performs final assessment in accordance with point 3.2 of Annex I.
——确定制造商确实根据附录 I 第 3.2 条进行最终评定。

— take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the pressure equipment samples.
——在制造或储存处抽取压力设备样品来进行检查。该公告机构评定设备部件的抽样数量，及是否有必要进行（或已进行）全部或部分压力设备样品的最终评定。

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits, with a view to ensuring conformity of the pressure equipment.
采纳抽样程序的目的是确定压力设备在制造过程中表现是否在允许范围，确保压力设备的符合性。

Should one or more of the items of pressure equipment or assembly not conform, the notified body shall take appropriate measures.
如果一个或多个压力设备或组合件部件不符合，公告机构应采取适当的措施。

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.
制造商应由公告机构负责，在制造过程中贴上公告机构的识别号。

5. CE marking and EU declaration of conformity
5、CE 标识与欧盟符合性声明
5.1. The manufacturer shall affix the CE marking to each individual pressure equipment that satisfies the applicable requirements of this Directive.
5.1、制造商应在满足本指令适用要求的每一个压力设备上贴上 CE 标识。

5.2. The manufacturer shall draw up a written EU declaration of conformity for the pressure equipment model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.
5.2、在压力设备投放市场后，制造商应在国内权威机构处理后，为压力设备类型制定一份书面的欧盟符合性声明，并与技术文件一同保存 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
应照相关机构要求，提供欧盟符合性声明副本。

6. Authorised representative
6、授权代表
The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 5 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

3. MODULE B: EU-TYPE EXAMINATION
3、模式 B：欧盟型式检验
3.1. EU-Type examination – production type
3.1、欧盟型式检验——生产型

1. EU-type examination — production type is the part of a conformity assessment procedure in which a notified body examines the technical design of the pressure equipment and verifies and attests that the technical design of the pressure equipment meets the requirements of this Directive.
1、欧盟型式检验-生产型是公告机构检验压力设备技术设计、并验证该压力设备技术设计符合本指令要求的合格评定程序的一部分。

2. EU-type examination — production type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of

the production envisaged, of the complete pressure equipment.
2、欧盟型式检验-生产型应包括通过对点 3 提到的技术文件和支持证据的审查，评定压力设备是否有足够的技术设计，再加上对代表生产设想的完整压力设备的样本检查。

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.
3、制造商应向他选择的单一公告机构提出欧盟型式检验申请。

The application shall include:
该申请应包括：

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
——制造商名称和地址，如果申请是由获授权的代表提出，代表的姓名和地址，

— a written declaration that the same application has not been lodged with any other notified body,
——相同申请没有被提交至其他任何公告机构的书面声明，

— the technical documentation. The technical documentation shall make it possible to assess the conformity of the pressure equipment with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall contain, wherever applicable, at least the following elements:
——技术文件。该技术文件应可以评定压力设备符合该指令相关要求，并应包括充分的风险分析和评定。技术文件应指定适用的要求，并涵盖评定相关的压力设备的设计、制造和操作。技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
——为理解图纸和图表及操作压力设备所需的描述和解释，
— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明

采用的部分，

— results of design calculations made, examinations carried out, etc.,
——设计计算的结果，进行的验证等，
— test reports,
——测试报告，
— information concerning the tests provided for in manufacture,
——关于制造过程中测试的信息，
— information concerning the qualifications or approvals required under points 3.1.2 and 3.1.3 of Annex I,
——关于附录 I 第 3.1.2 和第 3.1.3 点要求的评定或批准信息
— the specimens representative of the production envisaged.
——代表生产设想的样品。

The specimen may cover several versions of the pressure equipment provided that the differences between the versions do not affect the level of safety.
样品可能覆盖多种型号的压力设备，但型号之间的不同不会影响安全等级。

The notified body may request further specimens if needed for carrying out the test programme;
如果试验计划需要，公告机构可能会要求更多样品；

— the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer applying other relevant technical specifications, or by another testing laboratory on his behalf and under his responsibility.
——充分的技术设计解决方案支持证据。该证据应提及任何用到的文件，特别是在相关协调标准不全适用的情况。支持证据在必要时应包括，由制造商采用其他相关技术规范，在合适实验室得到的测试结果，或以他的名义和责任下，在另一个测试实验室进行的测试。

4. The notified body shall:
4、公告机构应：

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the pressure equipment and the manufacturing procedures.
4.1、检查技术文件和支持证据，以评价压力设备及生产过程技术设计的充分性。

In particular, the notified body shall:
公告机构应特别：

— assess the materials where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,

——评估不符合相关协调标准或欧洲压力设备材料批准的材料，并根据附录 I 第 4.3 点检查材料制造商签发的证书，

— approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with point 3.1.2 of Annex I,

——批准压力设备零件永久性连接程序，或者按照附录 I 第 3.1.2 点检查此前已批准的程序，

— verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with points 3.1.2 or 3.1.3 of Annex I.

——验证根据附录 I 第 3.1.2 或 3.1.3 点进行评定或批准的进行压力设备零件永久性连接和无损检测的人员。

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards as well as the elements which have been designed using other relevant technical specifications without applying the relevant provisions of those standards.

4.2、验证已制造的试样符合技术文件，并确定根据相关协调标准规定设计的元素，及使用其他技术规范、没有使用相关标准规定的元素。

4.3. carry out appropriate examinations and necessary tests to check whether when the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly.

4.3、进行适当的检查和必要的测试，以检查是否制造商选择及正确了使用相关协调标准的方案。

4.4. carry out appropriate examinations and necessary tests to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive.

4.4、当未采用相关协调标准的方案时，需进行适当的检查和必要的测试，以检查制造商是否采用其他相关技术规范，来满足本指令相应的基本安全要求。

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

4.5、同意制造商某一地点进行检查和测试。

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authority, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

5、公告机构应编制按照第 4 点进行的活动记录及结果的评定报告。在不违背公告监管机构义务的情况下，公告机构应在制造商同意的条件下，全部或部分公开该报告的内容。

6. Where the type meets the requirements of this Directive, the notified body shall issue an

EU-type examination certificate – production type to the manufacturer. Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.
6、当满足本指令要求时，公告机构应当给制造商出具欧盟型式检验——生产型的证书。在不损害第 7 点时， 证书有效期为 10 年，到期更新，并应包括制造商名称和地址，检验结论和鉴别型式批准所需的必要数据。

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.
相关技术文件的有关部分的列表应附在证书上，并由公告机构保存。

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pressure equipment with the examined type to be evaluated and to allow for in-service control.
证书及其附录应包含所有相关的信息，以允许制造的压力设备及检查类型的符合性可以被评估，并允许在役控制。

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate – production type and shall inform the applicant accordingly, giving detailed reasons for its refusal. Provision shall be made for an appeals procedure.
当类型不符合本指令适用要求时，公告机构应拒绝签发欧盟型式检验——生产型证书，并应相应通知申请人，并详细告知拒绝的原因。应规定上诉程序。

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
7、公告机构应了解普遍认可工艺的任何变化， 以防已批准的类型可能不再符合本指令的适用要求，并应确认这些变化是否需要进一步调查。如果是的话，公告机构应相应通知制造商。

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate – production type of all modifications to the approved type that may affect the conformity of the pressure equipment with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU- type examination certificate – production type.
制造商应告知公告机构（Notified Body，如阿拜维 APAVE）所有已获得欧盟型式检验——生产型批准型号产品相关技术文件的修改，这可能会影响本指令压力设备基本安全要求的符合性或证书条件的有效性。这种修改应需要额外的批准，作为原始欧盟型式检验——生产型证书的补充。

8. Each notified body shall inform its notifying authority concerning the EU-type examination

certificates – production type and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.
8、公告机构应告知其公告主管机构关于欧盟型式检验——生产型证书，和/或其已发出或撤回的任何补充，并应定期或根据要求，通知公告主管机构其证书和/或任何增加、拒绝、暂停或其他限制。

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates –production type and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.
公告机构应告知其他公告机构其于欧盟型式检验——生产型证书，和/或任何增加、拒绝、暂停或其他限制，如有要求，告知已发出的相关证书和/或其补充。

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates – production type and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate – production type, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.
委员会、成员国和其他公告机构可要求得到欧盟型式检验——生产型证书的副本，和/或补充文件。委员会、成员国可要求获得公告机构的技术文件副本和检验的结果。公告机构应持有欧盟型式检验——生产型证书及其附录和补充文件的副本，以及包括由制造商提供的技术文件，直到证书有效期届满。

9. The manufacturer shall keep a copy of the EU-type examination certificate – production type, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.
9、在压力设备投放市场后，制造商应在公告监管机构处理后，保存欧盟型式检验——生产型证书及其附录和补充文件的副本 10 年。

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.
10、只要他们被任命书中指定，制造商授权代表可以进行第 3 点提到的申请，并执行在第 9 和第 7 点规定的义务。

3.2. EU-Type examination – design type
3.2、欧盟型式检验——设计型
1. EU-type examination – design type is the part of a conformity assessment procedure in which a notified body examines the technical design of the pressure equipment and verifies and attests that the technical design of the pressure equipment meets the requirements of this Directive.
1、欧盟型式检验——设计型是公告机构检验压力设备技术设计、并验证该压力设备技术设

计符合本指令要求的合格评定程序的一部分。

2. The EU-type examination – design type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen.
2、欧盟型式检验——设计型应包括通过对点 3 提到的技术文件和支持证据的审查，评定压力设备是否有足够的技术设计，而不检查样品。

The experimental design method provided for in point 2.2.4 of Annex I shall not be used in the context of this module.
附录 I 第 2.2.4 点规定的实验设计方法不可用于该模式。

3. The manufacturer shall lodge an application for EU-type examination — design type with a single notified body of his choice.
3、制造商应向他选择的单一公告机构提出欧盟型式检验——设计型申请。

The application shall include:
该申请应包括：

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
——制造商名称和地址，如果申请是由获授权的代表提出，代表的姓名和地址，

— a written declaration that the same application has not been lodged with any other notified body,
——相同申请没有被提交至其他任何公告机构的书面声明，

— the technical documentation. The technical documentation shall make it possible to assess the conformity of the pressure equipment with the applicable requirements of the Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall contain, wherever applicable, at least the following elements:
——技术文件。该技术文件应可以评定压力设备符合相关要求，并应包括充分的风险分析和评定。技术文件应指定适用的要求，并涵盖评定相关的压力设备的设计、制造和操作。技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

——为理解图纸和图表及操作压力设备所需的描述和解释，

— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，

— results of design calculations made, examinations carried out, etc.,

——设计计算的结果，进行的验证等，

— information regarding the qualifications or approvals required under points 3.1.2 and 3.1.3 of Annex I,

——关于附录 I 第 3.1.2 和第 3.1.3 点要求的评定或批准信息

— the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. This supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.

—充分的技术设计解决方案支持证据。该证据应提及任何用到的文件，特别是在相关协调标准不全适用的情况。支持证据在必要时应包括，由制造商在合适实验室得到的测试结果，或以他的名义和责任下，在另一个测试实验室进行的测试。

The application may cover several versions of the pressure equipment provided that the differences between the versions do not affect the level of safety.

样品可能覆盖多种型号的压力设备，但型号之间的不同不会影响安全等级。

4. The notified body shall:

4、公告机构应：

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product.

4.1、检查技术文件和支持证据，以评价压力设备及生产过程技术设计的充分性。

In particular, the notified body shall:

公告机构应特别：

— assess the materials where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials,

——评估不符合相关协调标准或欧洲压力设备材料批准的材料，

— approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with point 3.1.2 of Annex I.

——批准压力设备零件永久性连接程序，或者按照附录 I 第 3.1.2 点检查此前已批准的程序，

4.2. carry out appropriate examinations to check whether where the manufacturer has chosen to apply the solutions in the relevant harmonised standards these have been applied correctly.
4.2、进行适当的检查，以检查是否制造商选择及正确了使用相关协调标准的方案。

4.3. carry out appropriate examinations to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive.
4.3、当未采用相关协调标准的方案时，需进行适当的检查，以检查制造商是否满足本指令相应的基本安全要求。

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
5、公告机构应编制按照第 4 点进行的活动记录及结果的评定报告。在不违背公告监管机构义务的情况下，公告机构应在制造商同意的条件下，全部或部分公开该报告的内容。

6. Where the design meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate — design type to the manufacturer. Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved design.
6、当满足本指令要求时，公告机构应当给制造商出具欧盟型式检验——设计型的证书。在不违背第 7 点的情况下， 证书有效期为 10 年，到期更新，并应包括制造商名称和地址，检验结论和鉴别设计批准所需的必要数据。

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.
相关技术文件的有关部分的列表应附在证书上，并由公告机构保存。

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pressure equipment with the examined design to be evaluated and to allow for in-service control.
证书及其附录应包含所有相关的信息，以允许制造的压力设备及检查类型的符合性可以被评估，并允许在役控制。

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate — design type and shall inform the applicant accordingly, giving detailed reasons for its refusal.
当类型不符合本指令适用要求时，公告机构应拒绝签发欧盟型式检验——设计型证书，并应相应通知申请人，并详细告知拒绝的原因。

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable

requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
7、公告机构应了解普遍认可工艺的任何变化， 以防已批准的类型可能不再符合本指令的适用要求，并应确认这些变化是否需要进一步调查。如果是的话，公告机构应相应通知制造商。

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate — design type of all modifications to the approved design that may affect the conformity of the pressure equipment with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate — design type.
制造商应告知公告机构（Notified Body，如阿拜维 APAVE）所有已获得欧盟型式检验——设计型批准型号产品相关技术文件的修改，这可能会影响本指令压力设备基本安全要求的符合性或证书条件的有效性。这种修改应需要额外的批准，作为原始欧盟型式检验——设计型证书的补充。

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates — design type and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.
8、公告机构应告知其公告主管机构关于欧盟型式检验——设计型证书，和/或其已发出或撤回的任何补充，并应定期或根据要求，通知公告主管机构其证书和/或任何增加、拒绝、暂停或其他限制。

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates — design type and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.
公告机构应告知其他公告机构其于欧盟型式检验——设计型证书，和/或任何增加、拒绝、暂停或其他限制，如有要求，告知已发出的相关证书和/或其补充。

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates — design type and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate — design type, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.
委员会、成员国和其他公告机构可要求得到欧盟型式检验——设计型证书的副本，和/或补充文件。委员会、成员国可要求获得公告机构的技术文件副本和检验的结果。公告机构应持有欧盟型式检验——设计型证书及其附录和补充文件的副本，以及包括由制造商提供的技术文件，直到证书有效期届满。

9. The manufacturer shall keep a copy of the EU-type examination certificate — design type, its

annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.
9、在压力设备投放市场后，制造商应在公告监管机构处理后，保存欧盟型式检验——设计型证书及其附录和补充文件的副本 10 年。

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.
10、只要他们被任命书中指定，制造商授权代表可以进行第 3 点提到的申请，并执行在第 9 和第 7 点规定的义务。

4. MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS
4、模式 C2：符合基于内部生产控制+随机间隔的压力设备检查监督

1. Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pressure equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to it.
1、符合基于内部生产控制+随机间隔的压力设备检查监督是合格评定程序的一部分，制造商满足以下第 2、3 和 4 条义务，并确保和宣布对他唯一的责任，相关压力设备符合欧盟型式检验证书类型的描述，并满足本指令适用的要求。

2. Manufacturing
2、制造
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.
制造商应采取一切必要的措施，确保生产的压力设备的制造过程及其监控符合欧盟型式检验证书的描述及本指令适用的要求。

3. Final assessment and pressure equipment checks
3、最终评定和压力设备检查
A notified body, chosen by the manufacturer, shall carry out checks or have them carried out at random intervals determined by the body, in order to verify the quality of the final assessment and of the internal checks on the pressure equipment, taking into account, inter alia, the technological complexity of the pressure equipment and the quantity of production.
由制造商选择的公告机构，应进行检查或由机构自行决定的随机检查，以验证最终评定和压力设备内部检查的质量，并应考虑到除其他因素外的压力设备技术复杂度和生产量。

The notified body shall establish that the manufacturer actually performs final assessment in

accordance with point3.2 of Annex I.
公告机构应依据附录 I 第 3.2 条，安排制造商实际执行最终评定。

An adequate sample of the final pressure equipment, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or equivalent tests applying other technical specifications, shall be carried out to check the conformity of the pressure equipment with the relevant requirements of this Directive.
在投放市场之前，公告机构应现场选取足够的最终压力设备样品，经适当的、协调标准相关部分要求的测试，和/或使用其他技术规范的等效试验，检查压力设备是否符合本指令的有关要求。

The notified body shall assess the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of final assessment on the pressure equipment samples.
公告机构（Notified Body，如阿拜维 APAVE）应评定取样设备部分的数量以及是否有必要进行或已进行全部或部分压力设备样品的最终评定。

Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.
当样品不符合可接受质量水平时，机构应采取适当的措施。

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits, with a view to ensuring conformity of the pressure equipment.
接受抽样程序的目的是确定压力设备制造过程是否在可接受范围内执行，以确保压力设备的一致性。

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.
当由公告机构进行试验时，制造商应在公告机构的名义下，在制造过程附上公告机构识别号。

4. CE marking and EU declaration of conformity
4、CE 标识与欧盟符合性声明

4.1. The manufacturer shall affix the CE marking to each individual pressure equipment or assembly that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
4.1、制造商应在满足本指令适用要求的每一个压力设备或组合件上贴上 CE 标识。这些设备需符合欧盟型式检验证书的描述及本指令适用的要求。。

4.2. The manufacturer shall draw up a written EU declaration of conformity for a pressure equipment model and keep it at the disposal of the national authorities for 10 years after the

pressure equipment has been placed on the market.
4.2、在压力设备投放市场后，制造商应在国内权威机构处理后，为压力设备类型制定一份书面的欧盟符合性声明，并保存 10 年。

The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.
欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
应照相关机构要求，提供欧盟符合性声明副本。

5. Authorised representative
5、授权代表
The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 4 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

5. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS
5、模式 D：基于生产过程质量保证

1. Conformity to type based on quality assurance of the production process is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment or assembly concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.
1、基于生产过程质量保证是合格评定程序的一部分，是指制造商满足第 2 点和第 5 点的义务，并保证和声明相关压力设备或组合件符合欧盟型式检验证书的描述，及本指令适用的要求唯一责任。

2. Manufacturing
2、制造

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pressure equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.
制造商应运行一个已批准的、用于生产、最终产品检验和测试第 3 点指定的相关压力设备的质量体系，并应受到第 4 点要求的监督。

3. Quality system
3、质量体系
3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pressure equipment concerned.

3.1、制造商应向其所选择的公告机构提出申请，评定相关压力设备质量体系。

The application shall include:
该申请应包括：

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
——制造商名称和地址，如果申请是由授权代表提出，则代表的姓名和地址，
— a written declaration that the same application has not been lodged with any other notified body,
——相同申请没有被提交至任何其他公告机构的书面声明，
— all relevant information on the pressure equipment type envisaged,
——所有有关压力设备类型的信息，
— the documentation concerning the quality system,
——质量体系相关文件，
— the technical documentation of the approved type and a copy of the EU-type examination certificate.
——已批准版本的技术文件和欧盟形式检验证书副本。

3.2. The quality system shall ensure that the pressure equipment is in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to it.
3.2、质量体系应确保压力设备与欧盟形式检验证书中所描述的类型一致，并符合本指令的适用要求。

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.
制造商所采用的所有元素、要求和规定应系统且有序地以书面政策、程序和说明形式记录。本质量体系文件应对质量方案、计划、手册和记录具有一致的解释。

It shall, in particular, contain an adequate description of:
它应特别涵盖（以下项目）充分的描述：

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
——质量目标和管理组织架构、关于压力设备质量管理职责和权力，

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,
——相应的制造、质量控制和质量保证技术、流程和将使用的系统行为，特别是按照附录 I 第 3.1.2 点用于永久性联接部分的批准程序，

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
——在制造过程前中后进行的检查和测试，以及实施频率，

— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc., and
——质量记录，如检验报告和测试数据、校准数据，有关人员资格或批准的报告，特别是根据附录 I 第 3.1.2 点和第 3.1.3 点，承担永久性联接和无损测试的人员，以及

— the means of monitoring the achievement of the required quality and the effective operation of the quality system.
——监控达到所需质量和质量系统有效运行的方法。

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.
3.3、公告机构应评定质量体系，以确定其是否满足第 3.2 点的要求。

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

它应假定符合这些要求的质量体系元素，符合相关协调标准的相应指标要求。

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an inspection visit to the manufacturer's premises.
除了质量管理体系的经验，审计团队应至少有一个成员具有相关压力设备领域和压力设备技术方面的评定经验，并了解本指令的适用要求。审核应包括对制造商场所的检验。

The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.
审核组应当审查 3.1 点第五段提到的技术文件，以验证制造商的能力，确定该指令有关要求，并进行必要的测试，确保产品符合这些要求。

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.
决定应通知制造商。通知应包含审核结果和合理的评估决定。

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as

approved and to maintain it so that it remains adequate and efficient.
3.4、制造商应有义务保证履行并保持质量体系，使它保持足够的和有效的。

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.
3.5、制造商应通知批准质量体系的公告机构任何改变质量体系的打算。

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.
公告机构（Notified Body，如阿拜维 APAVE）应评定草拟的更改，并决定修改后的质量体系是否继续符合 3.2 点的要求，或是有必要重新评定。

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
它应通知制造商其决定。并应通知审核结果和合理的评估决定。

4. Surveillance under the responsibility of the notified body
4、公告机构负责的监督

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
4.1、监督的目的是确保制造商正式履行了批准的质量体系所产生的义务。

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
4.2、作为评定的目的，制造商应为允许公告机构进入制造、检验、测试和仓储过程，并应提供所有的必要信息，特别是：

— the quality system documentation,
——质量体系文件，
— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
——质量记录，如检验报告、测试数据、校准数据、相关人员的合格报告等。

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
4.3、公告机构应定期进行审核，以确保制造商保持和实施质量体系，并为制造商提供审核报告。定期评审的频率应为每三年进行一次全面重新评审。

4.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for

such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:
4.4、此外，公告机构可对制造商进行不定期突击访问。这种额外访问的需求和频率，将在访问控制体系的基础上，由公告机构确定。访问控制体系应特别考虑以下因素：

— the category of the pressure equipment,
——压力设备的种类，
— the results of previous surveillance visits,
——之前监督访问的结果，
— the need to follow up corrective actions,
——跟进纠正措施的必要性，
— special conditions linked to the approval of the system, where applicable,
——适用时，体系批准的特殊条件，
— significant changes in manufacturing organisation, policy or techniques.
——制造组织架构、政策或技术的重大变化。

During such visits the notified body may, if necessary, carry out product tests or have them carried out in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
在访问期间，如有必要，公告机构（Notified Body，如阿拜维 APAVE）应进行产品测试，以验证质量体系是否正常运行。公告机构应向制造商提供访问报告。如果进行了测试，提供测试报告。

5. CE marking and EU declaration of conformity
5、CE 标识与欧盟符合性声明

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pressure equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
5.1、制造商应在每一个符合欧盟型式检验证书描述及本指令适用要求的压力设备上贴上 CE 标识及，在第 3.1 点提到的公告机构（Notified Body，如阿拜维 APAVE）负责下，附上机构编码。

5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.
5.2、在压力设备投放市场后，制造商应在国内权威机构处理后，为压力设备类型制定一份书面的欧盟符合性声明，并保存 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities

upon request.
应照相关机构要求，提供欧盟符合性声明副本。

6. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
6、在压力设备投放市场后，制造商应在国内权威机构处理后，保存以下文件 10 年：

— the documentation referred to point 3.1,
——第 3.1 点提到的文件，
— the change referred to in point 3.5, as approved,
——如经批准，第 3.5 点提到的变更，
— the decisions and reports of the notified body referred to in points 3.3, 3.5, 4.3 and 4.4.
——在第 3.3、3.5、4.3 和 4.4 点提到的公告机构决定和报告。

7. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.
7、公告机构应告知其公告主管机构关于质量体系的批准和撤回，并应定期或根据要求，通知公告主管机构其批准的质量体系拒绝、暂停或其他限制清单。

Each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.
公告机构应告知其他公告机构其质量体系批准的拒绝、暂停或其他限制，如有要求，告知已发出的质量体系批准。

8. Authorised representative
8、授权代表
The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 3.1，3.5，5 和 6 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

6. MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS
6、模式 D1：生产过程中质量保证

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive that apply to it.
1、生产过程中质量保证是合格评定程序，是指制造商满足第 2 点、第 4 点和第 7 点的义务，并保证和声明相关压力设备或组合件符合本指令适用的要求唯一责任。

2. Technical documentation

2、技术文件

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

制造商应建立技术文件。该技术文件应可以评定压力设备符合相关要求，并应包括充分的风险分析和评定。技术文件应指定适用的要求，并涵盖评定相关的压力设备的设计、制造和操作。技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,

——压力设备大致描述，

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

——概念设计和组件的制造图纸和图表、分组件、电路等，

— descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,

——为理解图纸和图表及操作压力设备所需的描述和解释，

— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，

— results of design calculations made, examinations carried out, etc., and

——设计计算的结果，进行的验证等，

— test reports.

——测试报告。

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.

3、在压力设备投放市场后，制造商应在国家有关部门处理后保存技术文件 10 年。

4. Manufacturing

4、制造

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pressure equipment concerned as specified in point 5, and shall be subject to surveillance as specified in point 6.

制造商应运行一个已批准用于生产，最终产品检验和测试第 5 点指定压力设备的质量体系，，并应按第 6 点受到监督。

5. Quality system
5、质量体系
5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pressure equipment concerned.
5.1、制造商应向其所选择的公告机构提出申请，评定相关压力设备质量体系。

The application shall include:
该申请应包括：

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
——制造商名称和地址，如果申请是由授权代表提出，则代表的姓名和地址，
— a written declaration that the same application has not been lodged with any other notified body,
——相同申请没有被提交至任何其他公告机构的书面声明，
— all relevant information on the pressure equipment type envisaged,
——所有有关压力设备类型的信息，
— the documentation concerning the quality system,
——质量体系相关文件，
— the technical documentation referred to in point 2.
——第 2 点提到的技术文件。

5.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.
5.2、质量体系应确保压力设备符合本指令的适用要求。

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.
制造商所采用的所有元素、要求和规定应系统且有序地以书面政策、程序和说明形式记录。本质量体系文件应对质量方案、计划、手册和记录具有一致的解释。

It shall, in particular, contain an adequate description of:
它应特别涵盖（以下项目）充分的描述：

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
——质量目标和管理组织架构、关于压力设备质量管理职责和权力，

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,

——相应的制造、质量控制和质量保证技术、流程和将使用的系统行为，特别是按照附录 I 第 3.1.2 点用于永久性联接部分的批准程序，

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
——在制造过程前中后进行的检查和测试，以及实施频率，

— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts in accordance with point 3.1.2 of Annex I, etc.,
——质量记录，如检验报告和测试数据、校准数据，有关人员资格或批准的报告，特别是根据附录 I 第 3.1.2 点和第 3.1.3 点，承担永久性联接和无损测试的人员，

— the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
——监控达到所需质量和质量系统有效运行的方法。

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in point 5.2.
5.3、公告机构应评定质量体系，以确定其是否满足第 5.2 点的要求。符合相关协调标准的质量体系元素推定符合第 5.2 点所指的相应要求。

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the pressure equipment technology concerned, and the knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.
除了质量管理体系的经验，审计团队应至少有一个成员具有相关压力设备领域和压力设备技术方面的评定经验，并了解本指令的适用要求。审核应包括对制造商场所的检验。

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.
审核组应当审查第 2 点提到的技术文件，以验证制造商的能力，确定该指令有关要求，并进行必要的测试，确保产品符合这些要求。

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.
决定应通知制造商。通知应包含审核结果和合理的评估决定。

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as

approved and to maintain it so that it remains adequate and efficient.
5.4、制造商应有义务保证履行并保持质量体系，使它保持足够的和有效的。

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.
5.5、制造商应通知批准质量体系的公告机构任何改变质量体系的打算。

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a reassessment is necessary.
公告机构（Notified Body，如阿拜维 APAVE）应评定草拟的更改，并决定修改后的质量体系是否继续符合 3.2 点的要求，或是有必要重新评定。

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
它应通知制造商其决定。并应通知审核结果和合理的评估决定。

6. Surveillance under the responsibility of the notified body
6、公告机构负责的监督

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
6.1、监督的目的是确保制造商正式履行了批准的质量体系所产生的义务。

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
6.2、作为评定的目的，制造商应为允许公告机构进入制造、检验、测试和仓储过程，并应提供所有的必要信息，特别是：

— the quality system documentation,
——质量体系文件，
— the technical documentation referred to in point 2,
——第 2 点所指的技术文件，
— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
——质量记录，如检验报告、测试数据、校准数据、相关人员的合格报告等。

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
6.3、公告机构应定期进行审核，以确保制造商保持和实施质量体系，并为制造商提供审核报告。定期评审的频率应为每三年进行一次全面重新评审。

6.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:
6.4、此外，公告机构可对制造商进行不定期突击访问。这种额外访问的需求和频率，将在访问控制体系的基础上，由公告机构确定。访问控制体系应特别考虑以下因素：

— the category of the pressure equipment,
——压力设备的种类，
— the results of previous surveillance visits,
——之前监督访问的结果，
— the need to follow up corrective actions,
——跟进纠正措施的必要性，
— special conditions linked to the approval of the system, where applicable,
——适用时，体系批准的特殊条件，
— significant changes in manufacturing organisation, policy or techniques.
——制造组织架构、政策或技术的重大变化。

During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
在访问期间，如有必要，公告机构（Notified Body，如阿拜维 APAVE）应进行产品测试，以验证质量体系是否正常运行。公告机构应向制造商提供访问报告。如果进行了测试，提供测试报告。

7. CE marking and EU declaration of conformity
7、CE 标识与欧盟符合性声明

7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual pressure equipment that satisfies the applicable requirements of this Directive.
7.1、制造商应在每一个符合本指令适用要求的压力设备上贴上 CE 标识及，在第 5.1 点提到的公告机构（Notified Body，如阿拜维 APAVE）负责下，附上机构编码。

7.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the product model for which it has been drawn up.
7.2、在压力设备投放市场后，制造商应在国内权威机构处理后，为压力设备类型制定一份书面的欧盟符合性声明，并保存 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities

upon request.
应照相关机构要求，提供欧盟符合性声明副本。

8. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
8、在压力设备投放市场后，制造商应在国内权威机构处理后，保存以下文件 10 年：

— the documentation referred to in point 5.1,
——第 5.1 点提到的文件，
— the change referred to in point 5.5,
——第 5.5 点提到的变更，
— the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.
——在第 5.5、6.3 和 6.4 点提到的公告机构决定和报告。

9. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall periodically, or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.
9、公告机构应告知其公告主管机构关于质量体系的批准和撤回，并应定期或根据要求，通知公告主管机构其批准的质量体系拒绝、暂停或其他限制清单。

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, or withdrawn, and upon request, of quality system approvals which it has issued.
公告机构应告知其他公告机构其质量体系批准的拒绝及撤回，如有要求，告知已发出的质量体系批准。

10. Authorised representative
10、授权代表
The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 3、5.1、5.5、7 和 8 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

7. MODULE E: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT QUALITY ASSURANCE
7、模式 E：符合基于压力设备质量保证型

1. Conformity to type based on pressure equipment quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.
1、符合基于压力设备质量保证型是合格评定程序的一部分，是指制造商满足第 2 点和第 5 点的义务，并保证和声明相关压力设备或组合件符合欧盟型式检验证书的描述，及本指令适

用的要求唯一责任。

2. Manufacturing
2、制造

The manufacturer shall operate an approved quality system for the final product inspection and testing of the pressure equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.
制造商应运行一个已批准的、用于生产、最终产品检验和测试第 3 点指定的相关压力设备的质量体系，并应受到第 4 点要求的监督。

3. Quality system
3、质量体系
3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.
3.1、制造商应向其所选择的公告机构提出申请，评定相关压力设备质量体系。

The application shall include:
该申请应包括：
— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
——制造商名称和地址，如果申请是由授权代表提出，则代表的姓名和地址，
— a written declaration that the same application has not been lodged with any other notified body,
——相同申请没有被提交至任何其他公告机构的书面声明，
— all relevant information on the pressure equipment type envisaged,
——所有有关压力设备类型的信息，
— the documentation concerning the quality system,
——质量体系相关文件，
— the technical documentation of the approved type and a copy of the EU-type examination certificate.
——已批准版本的技术文件和欧盟形式检验证书副本。

3.2. The quality system shall ensure compliance of the products with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.
3.2、质量体系应确保压力设备与欧盟形式检验证书中所描述的类型一致，并符合本指令的适用要求。

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.
制造商所采用的所有元素、要求和规定应系统且有序地以书面政策、程序和说明形式记录。本质量体系文件应对质量方案、计划、手册和记录具有一致的解释。

It shall, in particular, contain an adequate description of:
它应特别涵盖（以下项目）充分的描述：

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
——质量目标和管理组织架构、关于产品质量管理职责和权力，

— the examinations and tests that will be carried out after manufacture,
—生产后将进行的检查和试验，
— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I,
——质量记录，如检验报告和测试数据、校准数据，有关人员资格或批准的报告，特别是根据附录 I 第 3.1.2 点和第 3.1.3 点，承担永久性联接和无损测试的人员，

— the means of monitoring the effective operation of the quality system.
——监控达到所需质量和质量系统有效运行的方法。

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.
3.3、公告机构应评定质量体系，以确定其是否满足第 3.2 点的要求。它应假定符合这些要求的质量体系元素，符合相关协调标准的相应指标要求。

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant pressure equipment field and pressure equipment technology concerned and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.
除了质量管理体系的经验，审计团队应至少有一个成员具有相关压力设备领域和压力设备技术方面的评定经验，并了解本指令的适用要求。审核应包括对制造商场所的检验。

The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.
审计组应当审查 3.1 点第五段提到的技术文件，以验证制造商的能力，确定该指令有关要求，并进行必要的测试，确保产品符合这些要求。

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.
决定应通知制造商。通知应包含审核结果和合理的评估决定。

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
3.4、制造商应有义务保证履行并保持质量体系，使它保持足够的和有效的。

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.
3.5、制造商应通知批准质量体系的公告机构任何改变质量体系的打算。

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.
公告机构（Notified Body，如阿拜维 APAVE）应评定草拟的更改，并决定修改后的质量体系是否继续符合 3.2 点的要求，或是有必要重新评定。

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
它应通知制造商其决定。并应通知审核结果和合理的评估决定。

4. Surveillance under the responsibility of the notified body
4、公告机构负责的监督

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
4.1、监督的目的是确保制造商正式履行了批准的质量体系所产生的义务。

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
4.2、作为评定的目的，制造商应为允许公告机构进入制造、检验、测试和仓储过程，并应提供所有的必要信息，特别是：

— the quality system documentation,
——质量体系文件，
— the technical documentation,
——技术文件，
— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.
——质量记录，如检验报告、测试数据、校准数据、相关人员的合格报告等。

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

4.3、公告机构应定期进行审核，以确保制造商保持和实施质量体系，并为制造商提供审核报告。定期评审的频率应为每三年进行一次全面重新评审。

4.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:
4.4、此外，公告机构可对制造商进行不定期突击访问。这种额外访问的需求和频率，将在访问控制体系的基础上，由公告机构确定。访问控制体系应特别考虑以下因素：

— the category of the pressure equipment,
——压力设备的种类，
— the results of previous surveillance visits,
——之前监督访问的结果，
— the need to follow up corrective actions,
——跟进纠正措施的必要性，
— special conditions linked to the approval of the system, where applicable,
——适用时，体系批准的特殊条件，
— significant changes in manufacturing organisation, policy or techniques.
——制造组织架构、政策或技术的重大变化。

During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
在访问期间，如有必要，公告机构（Notified Body，如阿拜维 APAVE）应进行产品测试，以验证质量体系是否正常运行。公告机构应向制造商提供访问报告。如果进行了测试，提供测试报告。

5. CE marking and EU declaration of conformity
5、CE 标识与欧盟符合性声明

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pressure equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
5.1、制造商应在每一个符合欧盟型式检验证书描述及本指令适用要求的压力设备上贴上 CE 标识及，在第 3.1 点提到的公告机构（Notified Body，如阿拜维 APAVE）负责下，附上机构编码。

5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the product model for which it has been drawn up.

5.2、在压力设备投放市场后，制造商在国内权威机构处理后，应为压力设备类型制定一份书面的欧盟符合性声明，并保存 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
应照相关机构要求，提供欧盟符合性声明副本。

6. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
6、在压力设备投放市场后，制造商应在国内权威机构处理后，保存以下文件 10 年：

— the documentation referred to point 3.1,
——第 3.1 点提到的文件，
— the change referred to in point 3.5, as approved,
——如经批准，第 3.5 点提到的变更，
— the decisions and reports of the notified body referred to in points 3.3, 3.5, 4.3 and 4.4.
——在第 3.3、3.5、4.3 和 4.4 点提到的公告机构决定和报告。

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.
7、公告机构应告知其公告主管机构关于质量体系的批准和撤回，并应定期或根据要求，通知公告主管机构其批准的质量体系拒绝、暂停或其他限制清单。

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.
公告机构应告知其他公告机构其质量体系批准的拒绝、暂停或撤回，如有要求，告知已发出的质量体系批准。

8. Authorised representative
8、授权代表
The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 3.1，3.5，5 和 6 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

8. MODULE E1: QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING
8、模式 E1：压力设备最终检验和测试的质量保证

1. Quality assurance of final pressure equipment inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the pressure equipment

concerned satisfy the requirements of this Directive that apply to it.
1、压力设备最终检验和测试的质量保证是指制造商满足第 2 点、第 4 点和第 7 点的义务，并保证和声明相关压力设备或组合件符合本指令适用的要求唯一责任。

2. Technical documentation
2、技术文件
The manufacturer shall establish the technical documentation. The technical documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s) The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall, wherever applicable, contain at least the following elements:
制造商应建立技术文件。该技术文件应可以评定压力设备符合相关要求，并应包括充分的风险分析和评定。技术文件应指定适用的要求，并涵盖评定相关的压力设备的设计、制造和操作。技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
——为理解图纸和图表及操作压力设备所需的描述和解释，
— a list of the harmonised standards, the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，
— results of design calculations made, examinations carried out, etc., and
——设计计算的结果，进行的验证等，和
— test reports.
——测试报告。

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.
3、在压力设备投放市场后，制造商应在国家有关部门处理后保存技术文件 10 年。

4. Manufacturing
4、制造
The manufacturer shall operate an approved quality system for the final product inspection and

testing of the pressure equipment as specified in point 5 and shall be subject to surveillance as specified in point 6.
制造商应运行一个已批准用于最终产品检验和测试第 5 点指定压力设备的质量体系，，并应按第 6 点受到监督。

5. Quality system
5、质量体系

5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.
5.1、制造商应向其所选择的公告机构提出申请，评定相关压力设备质量体系。

The application shall include:
该申请应包括：

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
——制造商名称和地址，如果申请是由授权代表提出，则代表的姓名和地址，
— a written declaration that the same application has not been lodged with any other notified body,
——相同申请没有被提交至任何其他公告机构的书面声明，
— all relevant information on the pressure equipment type envisaged,
——所有有关压力设备类型的信息，
— the documentation concerning the quality system,
——质量体系相关文件，
— the technical documentation referred to in point 2.
——第 2 点提到的技术文件。

5.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.
5.2、质量体系应确保压力设备符合本指令的适用要求。

Under the quality system, each item of pressure equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 12, or equivalent tests, and particularly final assessment as referred to in point 3.2 of Annex I, shall be carried out in order to ensure its conformity with the requirements of this Directive which apply to it.
在质量体系下，每个压力设备应检查并进行在第 12 条中提到的相关标准的合适测试，或其他等效测试。特别是应进行附录 I 第 3.2 点指的最终评定，以确保其符合本指令的适用要求。

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.
制造商所采用的所有元素、要求和规定应系统且有序地以书面政策、程序和说明形式记录。

本质量体系文件应对质量方案、计划、手册和记录具有一致的解释。

It shall, in particular, contain an adequate description of:
它应特别涵盖（以下项目）充分的描述：

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
——质量目标和管理组织架构、关于压力设备质量管理职责和权力，

— the procedures used for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,
——按照附录 I 第 3.1.2 点批准的、用于永久性联接部分的程序，

— the examinations and tests that will be carried out after manufacture,
——生产后进行的检查和试验，

— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts in accordance with point 3.1.2 of Annex I,
——质量记录，如检验报告和测试数据、校准数据，有关人员资格或批准的报告，特别是根据附录 I 第 3.1.2 点和第 3.1.3 点，承担永久性联接和无损测试的人员，

— the means of monitoring the effective operation of the quality system.
——监控质量体系有效运行的手段。

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.
5.3、公告机构应评定质量体系，以确定其是否满足第 5.2 点的要求。

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.
符合相关协调标准的质量体系元素推定符合相应要求。

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.
除了质量管理体系的经验，审计团队应至少有一个成员具有相关压力设备领域和压力设备技术方面的评定经验，并了解本指令的适用要求。审核应包括对制造商场所的检验。

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

审核组应当审查第 2 点提到的技术文件，以验证制造商的能力，确定该指令有关要求，并进行必要的测试，确保产品符合这些要求。

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.
决定应通知制造商。通知应包含审核结果和合理的评估决定。

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
5.4、制造商应有义务保证履行并保持质量体系，使它保持足够的和有效的。

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.
5.5、制造商应通知批准质量体系的公告机构任何改变质量体系的打算。

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a reassessment is required.
公告机构（Notified Body，如阿拜维 APAVE）应评定草拟的更改，并决定修改后的质量体系是否继续符合 3.2 点的要求，或是要求重新评定。

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
它应通知制造商其决定。并应通知审核结果和合理的评估决定。

6. Surveillance under the responsibility of the notified body
6、公告机构负责的监督

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
6.1、监督的目的是确保制造商正式履行了批准的质量体系所产生的义务。

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
6.2、作为评定的目的，制造商应为允许公告机构进入制造、检验、测试和仓储过程，并应提供所有的必要信息，特别是：

— the quality system documentation,
——质量体系文件，
— the technical documentation referred to in point 2,
——第 2 点所指的技术文件，
— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

——质量记录，如检验报告、测试数据、校准数据、相关人员的合格报告等。

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
6.3、公告机构应定期进行审核，以确保制造商保持和实施质量体系，并为制造商提供审核报告。定期评审的频率应为每三年进行一次全面重新评审。

6.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:
6.4、此外，公告机构可对制造商进行不定期突击访问。这种额外访问的需求和频率，将在访问控制体系的基础上，由公告机构确定。访问控制体系应特别考虑以下因素：

— the category of the equipment,
——设备的种类，
— the results of previous surveillance visits,
——之前监督访问的结果，
— the need to follow up corrective action(s),
——跟进纠正措施的必要性，
— special conditions linked to the approval of the system, where applicable,
——适用时，体系批准的特殊条件，
— significant changes in manufacturing organisation, policy or techniques.
——制造组织架构、政策或技术的重大变化。

During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
在访问期间，如有必要，公告机构（Notified Body，如阿拜维 APAVE）应进行产品测试，以验证质量体系是否正常运行。公告机构应向制造商提供访问报告。如果进行了测试，提供测试报告。

7. CE marking and EU declaration of conformity
7、CE 标识与欧盟符合性声明

7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual item of pressure equipment that satisfies the applicable requirements of this Directive.
7.1、制造商应在每一个符合欧盟型式检验证书描述及本指令适用要求的压力设备部分上贴上 CE 标识及，在第 5.1 点提到的公告机构（Notified Body，如阿拜维 APAVE）负责下，附上

机构编码。

7.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.
7.2、在压力设备投放市场后，制造商应在国内权威机构处理后，为压力设备类型制定一份书面的欧盟符合性声明，并保存 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。起来。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
应照相关机构要求，提供欧盟符合性声明副本。

8. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
8、在压力设备投放市场后，制造商应在国内权威机构处理后，保存以下文件 10 年：

— the documentation referred to in point 5.1,
——第 5.1 点提到的文件，
— the change referred to in point 5.5, as approved,
——批准后第 5.5 点提到的变更，
— the decisions and reports of the notified body referred to in points 5.3, 5.5, 6.3 and 6.4.
——在第 5.3、5.5、6.3 和 6.4 点提到的公告机构决定和报告。

9. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn and shall periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.
9、公告机构应告知其公告主管机构关于质量体系的批准和撤回，并应定期或根据要求，通知公告主管机构其批准的质量体系拒绝、暂停或其他限制清单。

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.
公告机构应告知其他公告机构其质量体系批准的拒绝及撤回，如有要求，告知已发出的质量体系批准。

10. Authorised representative
10、授权代表
The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 3、5.1、5.5、7 和 8 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

9. MODULE F: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT VERIFICATION
9、模式 F：基于压力设备验证的符合型

1. Conformity to type based on pressure equipment verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned, which has been subject to the provisions of point 3, is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive which apply to it.
1、基于压力设备验证的符合型是合格评定程序的一部分，是指制造商满足第 2 点和第 5 点的义务，并保证和声明相关属于第 3 点法规的压力设备符合欧盟型式检验证书的描述，及本指令适用的要求唯一责任。

2. Manufacturing
2、制造
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the requirements of this Directive which apply to them.
制造商应采取一切必要的措施，使制造产品的制造过程及其监控符合批准的欧盟型式检验证书描述，及本指令的适用要求。

3. Verification
3、验证
A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests in order to check the conformity of the pressure equipment with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.
由制造商选择的公告机构，应进行适当检查和测试，以检查压力设备符合批准的欧盟型式检验证书描述，及本指令的适用要求。

The examinations and tests to check the conformity of the pressure equipment with the appropriate requirements shall be carried out by examination and testing of every product as specified in point 4.
通过检查和试验以验证压力设备符合合适的要求，应按第 4 点要求的，对每个产品进行检查和试验。

4. Verification of conformity by examination and testing of every item of pressure equipment
4、通过对每个压力设备检验和测试进行符合性验证

4.1. All pressure equipment shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) or equivalent tests shall be carried out in order to verify conformity with the approved type and described in the EU-type examination certificate and with

the appropriate requirements of this Directive. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.
4.1、所有压力设备应逐个进行相关协调标准要求的检查和适当的测试（或等效试验），以检查符合及欧盟型式检验证书批准类型和描述，及本指令的适用要求。若没有协调标准时，相关公告机构应决定进行适当的测试。

In particular, the notified body shall:
公告机构应特别：

— verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with points 3.1.2 and 3.1.3 of Annex I,
——验证根据附录 I 第 3.1.2 或 3.1.3 点评定或批准的进行压力设备零件永久性连接和无损测试的人员，
— verify the certificate issued by the materials manufacturer in accordance with point 4.3 of Annex I,
——根据附录 I 第 4.3 点，验证材料制造商出具的证书，
— carry out or have carried out the final inspection and proof test referred to in point 3.2 of Annex I and examine the safety devices, if applicable.
——若可以，进行附录 I 第 3.2 点提到的最终检验和验证测试并检查安全装置。

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number or have it affixed under its responsibility to each approved item of pressure equipment.
4.2、公告机构应对进行的检查和测试颁发合格证书，并应在每一个被批准的压力设备部分上贴上其机构编号或对已附上的（设备）负责。

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the pressure equipment has been placed on the market.
在压力设备投放市场后，制造商应将合格证书保存 10 年，以供国家权威机构检验。

5. CE marking and EU declaration of conformity
5、CE 标识与欧盟符合性声明
5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual item of pressure equipment that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
5.1、制造商应在每一个符合欧盟型式检验证书描述及本指令适用要求的压力设备上贴上 CE 标识及，在第 3 点提到的公告机构（Notified Body，如阿拜维 APAVE）负责下，附上机构编码。

5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities, for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

5.2、在压力设备投放市场后，制造商应在国内权威机构处理后，为压力设备类型制定一份书面的欧盟符合性声明，并保存 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
应照相关机构要求，提供欧盟符合性声明副本。

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the pressure equipment.
如果第 3 点提到的公告机构（Notified Body，如阿拜维 APAVE）同意并对其负责，制造商也可以在压力设备上附上公告机构的机构编码。

6. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the pressure equipment during the manufacturing process.
6、如果第 3 点提到的公告机构（Notified Body，如阿拜维 APAVE）同意并对其负责，制造商也可以在生产过程中，对压力设备附上公告机构的机构编码。

7. Authorised representative
7、授权代表
The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2.
制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。授权代表可能不满足第 2 点要求的制造商义务。

10. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION
10、模式 G：基于单个设备的验证认可

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.
1、基于单个设备的验证认可是一种合格评定程序，指制造商满足第 2 点、第 3 点和第 5 点的义务，并保证和声明属于规定第 4 点的相关压力设备符合本指令适用的要求唯一责任。

2. Technical documentation
2、技术文件

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4.
制造商应制定技术文件，并提供给第 4 点提到的公告机构（Notified Body，如阿拜维 APAVE）。

The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements and shall include an adequate analysis and assessment of the

risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment.
技术文件应可以评定压力设备符合相关要求，并应包括充分的风险分析和评定。技术文件应指定适用的要求，并涵盖评定相关的压力设备的设计、制造和操作。

The technical documentation shall, wherever applicable, contain at least the following elements:
技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,
——为理解图纸和图表及操作压力设备所需的描述和解释，
— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards, have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，
— results of design calculations made, examinations carried out, etc.,
——设计计算的结果，进行的验证等，
— test reports,
——测试报告，
— appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the personnel concerned in accordance with points 3.1.2 and 3.1.3 of Annex I.
——有关生产和测试程序的批准及附录 I 第 3.1.2 和 3.1.3 条要求的相关人员评定或批准的详细资料。

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.
在压力设备投放市场后，制造商应在国内权威机构处理后保存技术文件 10 年。

3. Manufacturing
3、制造
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment with the applicable requirements of this Directive.
制造商应采取一切必要的措施，确保所制造的压力设备在制造过程及其监控符合本指令的要

求。

4. Verification

4、验证

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standard(s) and/or equivalent tests, to check the conformity of the pressure equipment with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out applying other technical specifications.

由制造商选择的公告机构，应进行相关协调标准要求的适当检查和测试、和/或等效测试，以检查压力设备符合本指令的适用要求。若没有协调标准时，相关公告机构应决定使用其他技术规范，进行适当的测试。

In particular the notified body shall:

公告机构应特别：

— examine the technical documentation with respect to the design and the manufacturing procedures,

——审核设计和制造程序的技术文件，

— assess the materials used where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,

——评估不符合相关协调标准或欧洲压力设备材料批准的材料，并根据附录 I 第 4.3 点检查材料制造商签发的证书，

— approve the procedures for the permanent joining of parts or check that they have been previously approved in accordance with point 3.1.2 of Annex I,

——批准零件永久性连接程序，或者按照附录 I 第 3.1.2 点检查此前已批准的程序，

— verify the qualifications or approvals required under points 3.1.2 and 3.1.3 of Annex I,

——审核附录 I 第 3.1.2 和第 3.1.3 条要求的资格或批准，

— carry out the final inspection referred to in point 3.2.1 of Annex I, perform or have performed the proof test referred to in point 3.2.2 of Annex I, and examine the safety devices, if applicable.

——若可以，进行附录 I 第 3.2.1 点提到的最终检验和附录 I 第 3.2.2 点提到的验证测试，并检查安全装置。

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved pressure equipment, or have it affixed under its responsibility. The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.

4.2、公告机构应对进行的检查和测试颁发合格证书，并应在被批准的压力设备上贴上其机构编号或对已附上编号的（设备）负责。在压力设备投放市场后，制造商应将合格证书保存 10 年，以供国家权威机构检验。

5. CE marking and EU declaration of conformity

5、CE 标识与欧盟符合性声明

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each item of pressure equipment that satisfies the applicable requirements of this Directive.
5.1、制造商应在每一个符合本指令适用要求的压力设备上贴上 CE 标识及，在第 4 点提到的公告机构负责下，附上机构编码。

5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.
5.2、在压力设备投放市场后，制造商应制定一份书面的欧盟符合性声明，在国内权威机构处理后存放 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
应照相关机构要求，提供欧盟符合性声明副本。

6. Authorised representative
6、授权代表
The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 2 和第 5 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

11. MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE
11、模式 H：基于全面质量保证的符合

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfies the requirements of this Directive that apply to it.
1、基于全面质量保证的符合是一种合格评定程序，是指制造商满足第 2 点和第 5 点的义务，并保证和声明相关压力设备或组合件符合本指令适用的要求唯一责任。

2. Manufacturing
2、制造

The manufacturer shall operate an approved quality system for design, manufacture, final product inspection and testing of the pressure equipment as specified in point 3 and shall be subject to surveillance as specified in point 4.
制造商应运行一个已批准的、用于设、生产、最终产品检验和测试第 3 点指定的相关压力设

备的质量体系，并应受到第 4 点要求的监督。

3. Quality system
3、质量体系

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.
3.1、制造商应向其所选择的公告机构提出申请，评定相关压力设备质量体系。

The application shall include:
该申请应包括：

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
——制造商名称和地址，如果申请是由授权代表提出，则代表的姓名和地址，
— the technical documentation for one model of each type of pressure equipment intended to be manufactured.
——每种需要制造的压力设备型号的技术文件。

The technical documentation shall, wherever applicable, contain at least the following elements:
技术文件应在适用的情况下，至少包含下列元素：
— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
——为理解图纸和图表及操作压力设备所需的描述和解释，
— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，
— results of design calculations made, examinations carried out, etc.,
——设计计算的结果，进行的验证等，
— test reports,
——测试报告，
— the documentation concerning the quality system, and
——质量体系的相关文件，以及

— a written declaration that the same application has not been lodged with any other notified body.
——相同申请没有被提交至任何其他公告机构的书面声明。

3.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.
3.2、质量体系应确保压力设备符合本指令的适用要求。

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.
制造商所采用的所有元素、要求和规定应系统且有序地以书面政策、程序和说明形式记录。本质量体系文件应对质量方案、计划、手册和记录具有一致的解释。

It shall, in particular, contain an adequate description of:
它应特别涵盖（以下项目）充分的描述：

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
——质量目标和管理组织架构、关于压力设备质量管理职责和权力，

— the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the pressure equipment will be met,
——应用的技术设计规范，包括标准，以及在相关协调标准不完全适用时，确保压力设备满足适用的指令基本要求的方法，

— the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment, pertaining to the product type covered, particularly with regard to materials in accordance with point 4 of Annex I,
——在设计压力设备时使用的设计控制和设计验证技术、生产过程和系统行为，涉及到产品类型，特别针对附录 I 第 4 点的材料，

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,
——相应的制造、质量控制和质量保证技术、流程和将使用的系统行为，特别是按照附录 I 第 3.1.2 点用于永久性联接部分的批准程序，

— the examinations and tests to be carried out before, during, and after manufacture, and the frequency with which they will be carried out,
——在制造过程前中后进行的检查和测试，以及实施频率，

— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc.,
——质量记录，如检验报告和测试数据、校准数据，有关人员资格或批准的报告，特别是根据附录 I 第 3.1.2 点和第 3.1.3 点，承担永久性联接和无损测试的人员，

— the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.
——监控达到所需设计及压力容器质量和质量系统有效运行的方法。

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.
3.3、公告机构应评定质量体系，以确定其是否满足第 3.2 点的要求。它应假定符合这些要求的质量体系元素，符合相关协调标准的相应指标要求。

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as assessor in the pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.
除了质量管理体系的经验，审计团队应至少有一个成员具有相关压力设备领域和压力设备技术方面的评定经验，并了解本指令的适用要求。审核应包括对制造商场所的检验。

The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.
审核组应当审查 3.1 点第 2 段提到的技术文件，以验证制造商的能力，确定该指令适用要求，并进行必要的测试，确保产品符合这些要求。

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.
制造商或其授权代表应得知该决定。通知应包含审核结论与合理的评估决定。

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
3.4、制造商应有义务保证履行并保持质量体系，使它保持足够的和有效的。

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.
3.5、制造商应通知批准质量体系的公告机构任何改变质量体系的打算。

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.
公告机构（Notified Body，如阿拜维 APAVE）应评定任何草拟的更改，并决定修改后的质量体系是否继续符合 3.2 点的要求，或是有必要重新评定。

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
它应通知制造商其决定。并应通知审核结果和合理的评估决定。

4. Surveillance under the responsibility of the notified body
4、公告机构负责的监督

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
4.1、监督的目的是确保制造商正式履行了批准的质量体系所产生的义务。

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
4.2、作为评定的目的，制造商应为允许公告机构进入制造、检验、测试和仓储过程，并应提供所有的必要信息，特别是：

— the quality system documentation,
——质量体系文件，
— the quality records provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
——质量记录，如检验报告、测试数据、校准数据、相关人员的合格报告等。
— the quality records provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
——由质量系统制造部门提供的质量记录，如检验报告和测试数据、校准数据、相关人员资格报告等。

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
4.3、公告机构应定期进行审核，以确保制造商保持和实施质量体系，并为制造商提供审核报告。定期评审的频率应为每三年进行一次全面重新评审。

4.4. In addition, the notified body may pay unexpected visits to the manufacturer.
4.4、此外，公告机构可对制造商进行不定期突击访问。

The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:
这种额外访问的需求和频率，将在访问控制体系的基础上，由公告机构确定。访问控制体系应特别考虑以下因素：

— the category of the equipment,
——压力设备的种类，
— the results of previous surveillance visits,
——之前监督访问的结果，
— the need to follow up corrective action(s),
——跟进纠正措施的必要性，
— special conditions linked to the approval of the system, where applicable,
——适用时，体系批准的特殊条件，
— significant changes in manufacturing organisation, policy or techniques.
——制造组织架构、政策或技术的重大变化。

During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
在访问期间，如有必要，公告机构（Notified Body，如阿拜维 APAVE）应进行产品测试，以验证质量体系是否正常运行。公告机构应向制造商提供访问报告。如果进行了测试，提供测试报告。

5. CE marking and EU declaration of conformity
5、CE 标识与欧盟符合性声明

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point3.1, the latter's identification number to each individual item of pressure equipment that satisfies the applicable requirements of this Directive.
5.1、制造商应在每一个符合本指令适用要求的压力设备上贴上 CE 标识及，在第 5.1 点提到的公告机构（Notified Body，如阿拜维 APAVE）负责下，附上机构编码。

5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.
5.2、制造商在压力设备投放市场后，应为压力设备类型制定一份书面的欧盟符合性声明，在国内权威机构处理后存放 10 年。欧盟符合性声明应明确需要拟定声明的压力设备。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
应照相关机构要求，提供欧盟符合性声明副本。

6. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
6、制造商在压力设备投放市场后，在国内权威机构处理后存放 10 年以下文件：

— the technical documentation referred to in point 3.1,
——第 3.1 点提到的文件，
— the documentation concerning the quality system referred to in point 3.1,
——如经批准，第 3.5 点提到的变更，
— the change referred to point 3.4, as approved,
——经批准的第 3.4 点所指的变更，
— the decisions and reports of the notified body referred to in points 3.3, 3.4, 4.3 and 4.4.
——在第 3.3、3.5、4.3 和 4.4 点提到的公告机构决定和报告。

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.
7、公告机构应告知其公告主管机构关于质量体系的批准和撤回，并应定期或根据要求，通知公告主管机构其批准的质量体系拒绝、暂停或其他限制清单。

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.
公告机构应告知其他公告机构其质量体系批准的拒绝、暂停或撤回，如有要求，告知已发出的质量体系批准。

8. Authorised representative
8、授权代表

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 3.1，3.5，5 和 6 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

12. MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION
12、模式 H1：

1. Conformity based on full quality assurance plus design examination and special surveillance of the final assessment is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of the Directive that apply to it.
1、基于全面质量保证+设计审查和最终评审特殊监管是合格评定程序，是指制造商满足第 2

点和第 6 点的义务，并保证和声明相关压力设备符合本指令适用的要求唯一责任。

2. Manufacturing
2、制造
The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 5.
制造商应运行一个已批准的、用于设计、生产、最终产品检验和测试第 3 点指定的相关压力设备的质量体系，并应受到第 5 点要求的监督。

The adequacy of the technical design of the pressure equipment shall have been examined in accordance with point 4.
应根据第 4 点检验压力设备技术设计的充分性。

3. Quality system
3、质量体系

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.
3.1、制造商应向其所选择的公告机构提出申请，评定相关压力设备质量体系。

The application shall include:
该申请应包括：

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
——制造商名称和地址，如果申请是由授权代表提出，则代表的姓名和地址，
— the technical documentation for one model of each type of pressure equipment intended to be manufactured.
——每种需要制造的压力设备型号的技术文件。

The technical documentation shall, wherever applicable, contain at least the following elements:
技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
——为理解图纸和图表及操作压力设备所需的描述和解释，
— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions

adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，
— results of design calculations made, examinations carried out, etc.,
——设计计算的结果，进行的验证等，
— test reports,
——测试报告，
— the documentation concerning the quality system,
——质量体系的相关文件，
— a written declaration that the same application has not been lodged with any other notified body.
——相同申请没有被提交至任何其他公告机构的书面声明，

3.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.
3.2、质量体系应确保压力设备符合本指令的适用要求。

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.
制造商所采用的所有元素、要求和规定应系统且有序地以书面政策、程序和说明形式记录。本质量体系文件应对质量方案、计划、手册和记录具有一致的解释。

It shall, in particular, contain an adequate description of:
它应特别涵盖（以下项目）充分的描述：

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
——质量目标和管理组织架构、关于压力设备质量管理职责和权力，

— the technical design specifications, including standards, that will be applied and, where relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential safety requirements of the Directive that apply to the pressure equipment will be met,
——应用的技术设计规范，包括标准，以及在相关协调标准不完全适用时，确保压力设备满足适用的指令基本要求的方法，

— the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment pertaining to the pressure equipment type covered, particularly with regard to materials in accordance with point 4 of Annex I,

——在设计压力设备时使用的设计控制和设计验证技术、生产过程和系统行为，涉及到产品类型，特别针对附录 I 第 4 点的材料，

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,
——相应的制造、质量控制和质量保证技术、流程和将使用的系统行为，特别是按照附录 I 第 3.1.2 点用于永久性联接部分的批准程序，

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
——在制造过程前中后进行的检查和测试，以及实施频率，

— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc.,
——质量记录，如检验报告和测试数据、校准数据，有关人员资格或批准的报告，特别是根据附录 I 第 3.1.2 点和第 3.1.3 点，承担永久性联接和无损测试的人员，

— the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.
——监控达到所需设计及压力容器质量和质量系统有效运行的方法。

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.
3.3、公告机构应评定质量体系，以确定其是否满足第 3.2 点的要求。

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard. In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.
它应假定符合这些要求的质量体系元素，符合相关协调标准的相应指标要求。除了质量管理体系的经验，审计团队应至少有一个成员具有相关压力设备领域和压力设备技术方面的评定经验，并了解本指令的适用要求。审核应包括对制造商场所的检验。

The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.
审核组应当审查 3.1 点第 2 段提到的技术文件，以验证制造商的能力，确定该指令适用要求，并进行必要的测试，确保产品符合这些要求。

The manufacturer or his authorised representative shall be notified of the decision.
制造商或其授权代表应得知该决定。

The notification shall contain the conclusions of the audit and the reasoned assessment decision.
通知应包含审核结论与合理的评估决定。

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
3.4、制造商应有义务保证履行并保持质量体系，使它保持足够的和有效的。

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.
3.5、制造商应通知批准质量体系的公告机构任何改变质量体系的打算。

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.
公告机构（Notified Body，如阿拜维 APAVE）应评定任何草拟的更改，并决定修改后的质量体系是否继续符合 3.2 点的要求，或是有必要重新评定。

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
它应通知制造商其决定。并应通知审核结果和合理的评估决定。

3.6. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.
3.6、公告机构应告知其公告主管机构关于质量体系的批准和撤回，并应定期或根据要求，通知公告主管机构其批准的质量体系拒绝、暂停或其他限制清单。

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.
公告机构应告知其他公告机构其质量体系批准的拒绝、暂停或撤回，如有要求，告知已发出的质量体系批准。

4. Design examination
4、设计审查

4.1. The manufacturer shall lodge an application for examination of the design of each item of pressure equipment not covered by a previous design examination with the notified body referred to in point 3.1.
4.1、制造商应针对每一款不被之前设计审查所覆盖的压力设备部件，向第 3.1 点提及的公告

机构提交申请。

4.2. The application shall make it possible to understand the design, manufacture and operation of the pressure equipment, and to assess the conformity with the requirements of this Directive that apply to it. It shall include:
4.2、申请应可以（让人）了解压力设备的设计、制造和操作，以评定是否符合本指令的适用要求。它应包括：

— the name and address of the manufacturer,
——制造商名称和地址，
— a written declaration that the same application has not been lodged with any other notified body,
——相同申请没有被提交至其他任何公告机构的书面声明，

— the technical documentation. The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).
——技术文件。该文件应可以评定压力设备符合相关要求，并应包括充分的风险分析和评定。

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design and operation of the pressure equipment. The technical documentation shall, wherever applicable, contain at least the following elements:
技术文件应指定适用的要求，并涵盖评定相关的压力设备的设计和操作。技术文件应视情况，至少包含以下元素：

— a general description of the pressure equipment,
——压力设备大致描述，
— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
——概念设计和组件的制造图纸和图表、分组件、电路等，
— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
——为理解图纸和图表及操作压力设备所需的描述和解释，
— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive, where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
——全部或部分引用已经发表在欧盟官方杂志的协调标准的列表，并描述所采取以满足协调标准没有要求的、本指令基本安全要求的解决方案。部分采用协调标准时，技术文件应指明采用的部分，
— results of design calculations made, examinations carried out, etc., and
——设计计算的结果，进行的验证等，
— test reports,

——测试报告，
— the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.
——充分的技术设计支持证据。该证据应提及任何用到的文件，特别是在相关协调标准不全适用的情况。支持证据在必要时应包括，由制造商采用其他相关技术规范，在合适实验室得到的测试结果，或以他的名义和责任下，在另一个测试实验室进行的测试。

4.3. The notified body shall examine the application, and where the design meets the requirements of this Directive that apply to the pressure equipment it shall issue an EU design examination certificate to the manufacturer. The certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. The certificate may have one or more annexes attached.
4.3、公告机构（Notified Body，如阿拜维 APAVE）应审查该申请，并当设计符合该压力设备相关本指令的要求时，应向制造商颁发欧盟设计证书。证书应包含制造商名称和地址，检查结论，有效（如果有的话）的条件和确定设计批准的必要数据。证书可含有一个或以上的附录。

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined design to be evaluated, and to allow for in-service control, where applicable.
如适用，证书及其附录应包含所有相关的信息，允许评估制造的产品与审查过的设计的一致性，并允许在役控制。

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.
当设计不符合本指令的适用要求时，公告机构应拒绝签发设计检验证书，并应酌情告知申请人，详细说明其拒绝的原因。

4.4. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
4.4、公告机构应了解普遍认可工艺的任何变化， 以防已批准的类型可能不再符合本指令的适用要求，并应确认这些变化是否需要进一步调查。如果是的话，公告机构应相应通知制造商。

The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential safety requirements of this Directive or the conditions for validity of the

certificate. Such modifications shall require additional approval — from the notified body that issued the EU design examination certificate — in the form of an addition to the original EU design examination certificate.
制造商应告知颁发欧盟设计审查证书的公告机构（Notified Body，如阿拜维 APAVE）任何可能影响已批准设计符合本指令基本安全要求或证书有效条件的修改。这种修改应需要颁发欧盟设计审查证书的公告机构额外的批准，作为原始欧盟设计审查证书的补充。

4.5. Each notified body shall inform its notifying authorities of the EU design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.
4.5、公告机构应告知其公告主管机构关于欧盟设计审查证书，和/或其已发出或撤回的任何补充，并应定期或根据要求，通知公告主管机构其证书和/或任何增加、拒绝、暂停或其他限制。

Each notified body shall inform the other notified bodies of the EU design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.
公告机构应告知其他公告机构其设计审查证书，和/或任何增加、拒绝、暂停或其他限制，如有要求，告知已发出的相关证书和/或其补充。

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.
委员会、成员国和其他公告机构可要求得到欧盟设计审查证书的副本，和/或补充文件。委员会、成员国可要求获得公告机构的技术文件副本和检验的结果。

The notified body shall keep a copy of the EU design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.
公告机构应持有欧盟设计审查证书及其附录和补充文件的副本，以及包括由制造商提供的技术文件，直到证书有效期届满。

4.6. The manufacturer shall keep a copy of the EU design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.
4.6、在压力设备投放市场后，制造商应在公告监管机构处理后，保存欧盟型式检验——生产型证书及其附录和补充文件的副本 10 年。

5. Surveillance under the responsibility of the notified body
5、公告机构负责的监督

5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
5.1、监督的目的是确保制造商正式履行了批准的质量体系所产生的义务。

5.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
5.2、作为评定的目的，制造商应为允许公告机构进入设计、制造、检验、测试和仓储过程，并应提供所有的必要信息，特别是：

— the quality system documentation,
——质量体系文件，
— the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
——质量记录，如检验报告、测试数据、校准数据、相关人员的合格报告等。
— the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
——由质量系统制造部门提供的质量记录，如检验报告和测试数据、校准数据，相关人员的资质报告等。

5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
5.3、公告机构应定期进行审核，以确保制造商保持和实施质量体系，并为制造商提供审核报告。定期评审的频率应为每三年进行一次全面重新评审。

5.4. In addition, the notified body may pay unexpected visits to the manufacturer.
5.4、此外，公告机构可对制造商进行不定期突击访问。

The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:
这种额外访问的需求和频率，将在访问控制体系的基础上，由公告机构确定。访问控制体系应特别考虑以下因素：

— the category of the equipment,
——设备的种类，
— the results of previous surveillance visits,
——之前监督访问的结果，
— the need to follow up corrective action(s),
——跟进纠正措施的必要性，
— special conditions linked to the approval of the system, where applicable,

——适用时，体系批准的特殊条件，
— significant changes in manufacturing organisation, policy or techniques.
——制造组织架构、政策或技术的重大变化。

During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
在访问期间，如有必要，公告机构（Notified Body，如阿拜维 APAVE）应进行产品测试，以验证质量体系是否正常运行。公告机构应向制造商提供访问报告。如果进行了测试，提供测试报告。

5.5. Special surveillance of the final assessment
5.5、最终评定的特殊监督

Final assessment as referred to in section 3.2 of Annex I is subject to increased surveillance in the form of unexpected visits by the notified body. In the course of such visits, the notified body shall conduct examinations on the pressure equipment.
根据附录 I 第 3.2 节所指的最终评定，以公告机构不定期突击访问的形式增加监督。在访问中，公告机构应当对压力设备检查。

It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
它应向制造商提供一个访问报告，如果测试已经进行，提供测试报告。

6. CE marking and EU declaration of conformity
6、CE 标识与欧盟符合性声明

6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual item of pressure equipment that satisfies the applicable requirements of this Directive.
6.1、制造商应在每一个符合本指令适用要求的压力设备上贴上 CE 标识及，在第 3.1 点提到的公告机构负责下，附上机构编码。

6.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up and shall mention the number of the design examination certificate.
6.2、制造商在压力设备投放市场后，应为压力设备类型制定一份书面的欧盟符合性声明，在国内权威机构处理后存放 10 年。欧盟符合性声明应明确需要拟定声明的压力设备并告知设计审查证书编号。

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

应照相关机构要求，提供欧盟符合性声明副本。

7. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
7、制造商在压力设备投放市场后，在国内权威机构处理后存放 10 年以下文件：

— the documentation concerning the quality system referred to in point 3.1,
——第 3.1 点提到的质量体系文件，
— the change referred to in point 3.5, as approved,
——如经批准，第 3.5 点提到的变更，
— the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.
——在第 3.5、5.3 和 5.4 点提到的公告机构决定和报告。

8. Authorised representative
8、授权代表

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.
第 4.1 和第 4.2 条所指的申请，以及第 3.1、第 3.5、第 4.4、第 4.6、第 6 和第 7 点提到的制造商义务可在授权书中特别规定，由他的授权代表代表他并在他负责下履行。

ANNEX IV
附录 IV

EU DECLARATION OF CONFORMITY (No XXXX) [1]
欧盟符合性声明（No XXXX）[1]

1. Pressure equipment or assembly (product, type, batch or serial number):
1、压力设备或组合件（产品，类型，批号或序列号）：

2. Name and address of the manufacturer and, where applicable, his authorised representative:
2、制造商的名称和地址，以及他的授权代表（如适用）：

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
3、制造商自行负责制定本符合性声明。

4. Object of the declaration (identification of pressure equipment or assembly allowing traceability; it may, where necessary for the identification of the pressure equipment or assembly, include an image):
4、声明的对象（具有可追溯性的压力设备或组合件标识；当有必要识别压力设备或组合件时，它可以包含图片）：

— description of the pressure equipment or assembly,
——压力设备或组合件的描述，
— conformity assessment procedure followed,
——合格评定程序，
— in the case of assemblies, description of the pressure equipment constituting the assembly, and the conformity assessment procedures followed,
——在组合件的情况下，描述构成组合件的压力设备以及合格评定程序，

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
5、以上声明目的是满足相关欧盟协调法规：

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
6、引用使用的相关协调标准，或引用符合性声明相关的其他技术文件：

7. Where appropriate, the name, address and number of the notified body which carried out the conformity assessment and the number of the certificate issued, and a reference to the EU-type examination certificate – production type, EU- type examination certificate – design type, EU design examination certificate or certificate of conformity.
7、当合适时，进行合格评定公告机构的名称、地址和编号和颁发证书的编号，以及引用欧盟型式检验证书—生产型，型式检验证书—设计型，或符合性证书。

8. Additional information:
8、附加信息：

Signed for and on behalf of:
(place and date of issue):
(name, function) (signature):
代表签署：
（地点和日期）：
（名称，函数）（签名）：

(where appropriate, particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative)
（当合适时，为制造商或其授权代表签订具有法律约束力的声明的授权签署细则）

(1) It is optional for the manufacturer to assign a number to the declaration of conformity.
（1）制造商为符合性声明分配一个编号是可选的。

ANNEX V
附录 V

PART A
A 部分
Repealed Directive with list of the successive amendments thereto (referred to in Article 50)
废除指令及其连续修订的清单（在第 50 条中提到的）

Directive 97/23/EC of the European Parliament and of the Council (OJ L 181, 9.7.1997, p. 1). 欧洲议会和理事会 97/23/EC 指令	
Regulation (EC) No 1882/2003 of the European Parliament and of the Council. (OJ L 284, 31.10.2003, p. 1). 欧洲议会和理事会 Regulation (EC) No 1882/2003 法规	Only point 13 of Annex I 只有附录 I 第 13 点
Regulation (EU) No 1025/2012 of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12). 欧洲议会和理事会 Regulation (EU) No 1025/2012 法规	Only point (f) of Article 26(1) 只有第 26 条第 1 款第 f 点

PART B
B 部分

Time-limit for transposition into national law and date of application (referred to in Article 49)
转为国家法律和申请日期的限制时间（在第 49 条中提到的）

Directive 指令	Time-limit for transposition 转换时间限制	Date of application 申请日期
97/23/EC	29 May 1999 1999 年 5 月 29 日	29 November 1999 (1) 1999 年 11 月 29 日

(1) In accordance with Article 20(3) of Directive 97/23/EC, Member States shall permit the putting into service of pressure equipment and assemblies which comply with the regulations in force in their territory at the date of application of the Directive beyond that date.

（1）根据 97/23/EC 指令第 20 条第（3）款，成员国应允许压力设备和组合件的投入服务，遵守在其领土上的规定，在该指令的应用之日起日期。

ANNEX VI

CORRELATION TABLE

对应表格

Directive 97/23/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)	Article 2(1) to (14)
Article 1(3)	Article 1(2)
—	Article 2(15) to (32)
Article 2	Article 3
Article 3	Article 4
Article 4(1)	Article 5(1)
Article 4(2)	Article 5(3)
—	Article 6
—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
Article 5	—
Article 6	—
—	Article 12(1)
Article 7(1)	Article 45
Article 7(2)	Article 44(1)
Article 7(3)	—
Article 7(4)	Article 44(5), second subparagraph
Article 8	—
Article 9(1)	Article 13(1), introductory sentence
Article 9(2) point 1	—
—	Article 13(1)(a)
Article 9(2) point 2	Article 13(1)(b)
Article 9(3)	Article 13(2)
Article 10	Article 14
Article 11(1)	Article 15(1)
Article 11(2)	Article 15(2)
Article 11(3)	Article 15(3)
Article 11(4)	Article 12(2)
—	Article 15(4)
Article 11(5)	Article 15(5)
—	Article 15(6)
Article 12	—
Article 13	—

Article 14(1)	Article 16(1)
Article 14(2)	Article 5(2)
Article 14(3) to (8)	Article 16(2) to (7)
Article 14(9) and (10)	—
—	Article 17
—	Article 18
Article 15(1)	—
Article 15(2)	Article 19(1)
Article 15(3)	Article 19(2)
Article 15(4) and (5)	—
—	Article 19(3) to (6)
—	Article 20
—	Article 21
—	Article 22
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Article 16	—
Article 17	—
Article 18	—
—	Article 39
—	Article 40
—	Article 41
—	Article 42
—	Article 43
—	Article 44(2) to (4)
—	Article 44(5), first subparagraph
—	Article 46
—	Article 47
Article 19	—

Article 20(1) to (2)	—
Article 20(3)	Article 48(1)
—	Article 48(2) and (3)
—	Article 49
—	Article 50
—	Article 51
Article 21	Article 52
Annex I	Annex I
Annex II	Annex II
Annex III, introductory wording	Annex III, introductory wording
Annex III, Module A	Annex III, point 1, Module A
Annex III, Module A1	Annex III, point 2, Module A2
Annex III, Module B	Annex III, point 3.1, Module B, EU-type examination – production type
Annex III, Module B1	Annex III, point 3.2, Module B, EU-type examination – design type
Annex III, Module C1	Annex III, point 4, Module C2
Annex III, Module D	Annex III, point 5, Module D
Annex III, Module D1	Annex III, point 6, Module D1
Annex III, Module E	Annex III, point 7, Module E
Annex III, Module E1	Annex III, point 8, Module E1
Annex III, Module F	Annex III, point 9, Module F
Annex III, Module G	Annex III, point 10, Module G
Annex III, Module H	Annex III, point 11, Module H
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Annex IV	—
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Annex VII	Annex IV
—	Annex V
—	Annex VI

STATEMENT OF THE EUROPEAN PARLIAMENT

The European Parliament considers that only when and insofar as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.