

Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast) (Text with EEA relevance)

CHAPTER 1

GENERAL PROVISIONS

Article 1	Scope
Article 2	Definitions
Article 3	Making available on the market and putting into service
Article 4	Technical requirements
Article 5	Free movement

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 6	Obligations of manufacturers
Article 7	Authorised representatives
Article 8	Obligations of importers
Article 9	Obligations of distributors
Article 10	Cases in which obligations of manufacturers apply to importers and distributors
Article 11	Identification of economic operators

CHAPTER 3

CONFORMITY AND CLASSIFICATION OF PRESSURE EQUIPMENT AND ASSEMBLIES

Article 12	Presumption of conformity
Article 13	Classification of pressure equipment
Article 14	Conformity assessment procedures
Article 15	European approval for materials
Article 16	User inspectorates
Article 17	EU declaration of conformity
Article 18	General principles of the CE marking
Article 19	Rules and conditions for affixing the CE marking

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 20	Notification
Article 21	Notifying authorities
Article 22	Requirements relating to notifying authorities
Article 23	Information obligation on notifying authorities

Article 24	Requirements relating to notified bodies and recognised third-party organisations
Article 25	Requirements relating to user inspectorates
Article 26	Presumption of conformity of conformity assessment bodies
Article 27	Subsidiaries of and subcontracting by conformity assessment bodies
Article 28	Application for notification
Article 29	Notification procedure
Article 30	Identification numbers and lists of notified bodies
Article 31	Lists of recognised third-party organisations and user inspectorates
Article 32	Changes to notifications
Article 33	Challenge of the competence of notified bodies, recognised third party organisations and user inspectorates
Article 34	Operational obligations of notified bodies, user inspectorates and recognised third party organisations
Article 35	Appeal against decisions of notified bodies, recognised third party organisations and user inspectorates
Article 36	Information obligation on notified bodies, recognised third party organisations and user inspectorates
Article 37	Exchange of experience
Article 38	Coordination of notified bodies, recognised third-party organisations and user inspectorates

CHAPTER 5

UNION MARKET SURVEILLANCE, CONTROL OF PRESSURE EQUIPMENT AND ASSEMBLIES ENTERING THE UNION MARKET, AND UNION SAFEGUARD PROCEDURE

Article 39	Union market surveillance and control of pressure equipment and assemblies entering the Union market
Article 40	Procedure for dealing with pressure equipment or assemblies presenting a risk at national level
Article 41	Union safeguard procedure
Article 42	Compliant pressure equipment or assemblies which present a risk
Article 43	Formal non-compliance

CHAPTER 6

COMMITTEE PROCEDURE AND DELEGATED ACTS

Article 44	Committee procedure
Article 45	Delegated power
Article 46	Exercise of the delegation

CHAPTER 7

TRANSITIONAL AND FINAL PROVISIONS

Article 47	Penalties
Article 48	Transitional provisions
Article 49	Transposition

Article 50	Repeal
Article 51	Entry into force and application
Article 52	Addressees

ANNEX I

ESSENTIAL SAFETY REQUIREMENTS

PRELIMINARY OBSERVATIONS

1. The obligations arising from the essential safety requirements listed in...
2. The essential safety requirements laid down in this Directive are...
3. The manufacturer is under an obligation to analyse the hazards...
4. The essential safety requirements are to be interpreted and applied...

1. GENERAL

- 1.1. Pressure equipment shall be designed, manufactured and checked, and if...
- 1.2. In choosing the most appropriate solutions, the manufacturer shall apply...
- 1.3. Where the potential for misuse is known or can be...

2. DESIGN

- 2.1. General
- 2.2. Design for adequate strength
 - 2.2.1. The pressure equipment shall be designed for loadings appropriate to...
 - 2.2.2. Design for adequate strength shall be based on either of...
 - 2.2.3. Calculation method
 - (a) Pressure containment and other loading aspects
 - (b) Resistance
 - (c) Stability aspects
 - 2.2.4. Experimental design method
- 2.3. Provisions to ensure safe handling and operation
- 2.4. Means of examination
 - (a) Pressure equipment shall be designed and constructed so that all...
 - (b) Means of determining the internal condition of the equipment shall...
 - (c) Other means of ensuring the safe condition of the pressure...
- 2.5. Means of draining and venting
- 2.6. Corrosion or other chemical attack
- 2.7. Wear
- 2.8. Assemblies
- 2.9. Provisions for filling and discharge
- 2.10. Protection against exceeding the allowable limits of pressure equipment
- 2.11. Safety accessories
 - 2.11.1. Safety accessories shall:
 - 2.11.2. Pressure limiting devices
 - 2.11.3. Temperature monitoring devices
- 2.12. External fire

3. MANUFACTURING

- 3.1. Manufacturing procedures
 - 3.1.1. Preparation of the component parts
 - 3.1.2. Permanent joining
 - 3.1.3. Non-destructive tests
 - 3.1.4. Heat treatment
 - 3.1.5. Traceability
- 3.2. Final assessment
 - 3.2.1. Final inspection
 - 3.2.2. Proof test
 - 3.2.3. Inspection of safety devices
- 3.3. Marking and labelling
- 3.4. Operating instructions
 - (a) When pressure equipment is made available on the market, it...
 - (b) Instructions shall cover information affixed to the pressure equipment in...
 - (c) If appropriate, these instructions shall also refer to risks arising...
- 4. MATERIALS
 - 4.1. Materials for pressurised parts shall:
 - 4.2. The pressure equipment manufacturer shall:
 - 4.3. The equipment manufacturer shall take appropriate measures to ensure that...

SPECIFIC PRESSURE EQUIPMENT REQUIREMENTS

- 5. FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH A RISK OF...
- 6. PIPING AS REFERRED TO IN ARTICLE 4(1)(c)
- 7. SPECIFIC QUANTITATIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT
 - 7.1. Allowable stresses
 - 7.1.1. Symbols
 - 7.1.2. The permissible general membrane stress for predominantly static loads and...
 - 7.2. Joint coefficients
 - 7.3. Pressure limiting devices, particularly for pressure vessels
 - 7.4. Hydrostatic test pressure
 - 7.5. Material characteristics

ANNEX II

CONFORMITY ASSESSMENT TABLES

- 1. The references in the tables to categories of modules are...
- 2. The safety accessories defined in point 4 of Article 2,...
- 3. The pressure accessories defined in point 5 of Article 2,...
- 4. The demarcation lines in the following conformity assessment tables indicate...

ANNEX III CONFORMITY ASSESSMENT PROCEDURES

The obligations arising from the provisions on pressure equipment in...

1. MODULE A: (INTERNAL PRODUCTION CONTROL)
 1. Internal production control is the conformity assessment procedure whereby the...
 2. Technical documentation
 3. Manufacturing
 4. CE marking and EU declaration of conformity
 - 4.1. The manufacturer shall affix the CE marking to each individual...
 - 4.2. The manufacturer shall draw up a written EU declaration of...
 5. Authorised representative
2. MODULE A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS...
 1. Internal production control plus supervised pressure equipment checks at random...
 2. Technical documentation
 3. Manufacturing
 4. Final assessment and pressure equipment checks
 5. CE marking and EU declaration of conformity
 - 5.1. The manufacturer shall affix the CE marking to each individual...
 - 5.2. The manufacturer shall draw up a written EU declaration of...
 6. Authorised representative
3. MODULE B: EU-TYPE EXAMINATION
 - 3.1. EU-Type examination – production type
 1. EU-type examination — production type is the part of a...
 2. EU-type examination — production type shall consist of an assessment...
 3. The manufacturer shall lodge an application for EU-type examination with...
 4. The notified body shall:
 5. The notified body shall draw up an evaluation report that...
 6. Where the type meets the requirements of this Directive, the...
 7. The notified body shall keep itself apprised of any changes...
 8. Each notified body shall inform its notifying authority concerning the...
 9. The manufacturer shall keep a copy of the EU-type examination...
 10. The manufacturer's authorised representative may lodge the application referred to...
 - 3.2. EU-Type examination – design type
 1. EU-type examination – design type is the part of a...
 2. The EU-type examination – design type shall consist of an...
 3. The manufacturer shall lodge an application for EU-type examination —...
 4. The notified body shall:
 5. The notified body shall draw up an evaluation report that...
 6. Where the design meets the requirements of this Directive, the...
 7. The notified body shall keep itself apprised of any changes...

8. Each notified body shall inform its notifying authorities concerning the...
 9. The manufacturer shall keep a copy of the EU-type examination...
 10. The manufacturer's authorised representative may lodge the application referred to...
4. **MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL...**
 1. Conformity to type based on internal production control plus supervised...
 2. Manufacturing
 3. Final assessment and pressure equipment checks
 4. CE marking and EU declaration of conformity
 - 4.1. The manufacturer shall affix the CE marking to each individual...
 - 4.2. The manufacturer shall draw up a written EU declaration of...
 5. Authorised representative
 5. **MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF...**
 1. Conformity to type based on quality assurance of the production...
 2. Manufacturing
 3. Quality system
 - 3.1. The manufacturer shall lodge an application for assessment of his...
 - 3.2. The quality system shall ensure that the pressure equipment is...
 - 3.3. The notified body shall assess the quality system to determine...
 - 3.4. The manufacturer shall undertake to fulfil the obligations arising out...
 - 3.5. The manufacturer shall keep the notified body that has approved...
 4. Surveillance under the responsibility of the notified body
 - 4.1. The purpose of surveillance is to make sure that the...
 - 4.2. The manufacturer shall, for assessment purposes, allow the notified body...
 - 4.3. The notified body shall carry out periodic audits to make...
 - 4.4. In addition the notified body may pay unexpected visits to...
 5. CE marking and EU declaration of conformity
 - 5.1. The manufacturer shall affix the CE marking and, under the...
 - 5.2. The manufacturer shall draw up a written EU declaration of...
 6. The manufacturer shall, for a period ending 10 years after...
 7. Each notified body shall inform its notifying authorities of the...
 8. Authorised representative
 6. **MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS**
 1. Quality assurance of the production process is the conformity assessment...
 2. Technical documentation
 3. The manufacturer shall keep the technical documentation at the disposal...
 4. Manufacturing
 5. Quality system
 - 5.1. The manufacturer shall lodge an application for assessment of his...
 - 5.2. The quality system shall ensure compliance of the pressure equipment...
 - 5.3. The notified body shall assess the quality system to determine...
 - 5.4. The manufacturer shall undertake to fulfil the obligations arising out...
 - 5.5. The manufacturer shall keep the notified body that has approved...
 6. Surveillance under the responsibility of the notified body
 - 6.1. The purpose of surveillance is to make sure that the...

- 6.2. The manufacturer shall, for assessment purposes, allow the notified body...
 - 6.3. The notified body shall carry out periodic audits to make...
 - 6.4. In addition the notified body may pay unexpected visits to...
 7. CE marking and EU declaration of conformity
 - 7.1. The manufacturer shall affix the CE marking and, under the...
 - 7.2. The manufacturer shall draw up a written EU declaration of...
 8. The manufacturer shall, for a period ending 10 years after...
 9. Each notified body shall inform its notifying authorities of the...
 10. Authorised representative
7. MODULE E: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT QUALITY...
 1. Conformity to type based on pressure equipment quality assurance is...
 2. Manufacturing
 3. Quality system
 - 3.1. The manufacturer shall lodge an application for assessment of his...
 - 3.2. The quality system shall ensure compliance of the products with...
 - 3.3. The notified body shall assess the quality system to determine...
 - 3.4. The manufacturer shall undertake to fulfil the obligations arising out...
 - 3.5. The manufacturer shall keep the notified body that has approved...
 4. Surveillance under the responsibility of the notified body
 - 4.1. The purpose of surveillance is to make sure that the...
 - 4.2. The manufacturer shall, for assessment purposes, allow the notified body...
 - 4.3. The notified body shall carry out periodic audits to make...
 - 4.4. In addition the notified body may pay unexpected visits to...
 5. CE marking and EU declaration of conformity
 - 5.1. The manufacturer shall affix the CE marking and, under the...
 - 5.2. The manufacturer shall draw up a written EU declaration of...
 6. The manufacturer shall, for a period ending 10 years after...
 7. Each notified body shall inform its notifying authorities of quality...
 8. Authorised representative
8. MODULE E1: QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND...
 1. Quality assurance of final pressure equipment inspection and testing is...
 2. Technical documentation
 3. The manufacturer shall keep the technical documentation at the disposal...
 4. Manufacturing
 5. Quality system
 - 5.1. The manufacturer shall lodge an application for assessment of his...
 - 5.2. The quality system shall ensure compliance of the pressure equipment...
 - 5.3. The notified body shall assess the quality system to determine...
 - 5.4. The manufacturer shall undertake to fulfil the obligations arising out...
 - 5.5. The manufacturer shall keep the notified body that has approved...
 6. Surveillance under the responsibility of the notified body
 - 6.1. The purpose of surveillance is to make sure that the...
 - 6.2. The manufacturer shall, for assessment purposes, allow the notified body...
 - 6.3. The notified body shall carry out periodic audits to make...
 - 6.4. In addition the notified body may pay unexpected visits to...

7. CE marking and EU declaration of conformity
 - 7.1. The manufacturer shall affix the CE marking and, under the...
 - 7.2. The manufacturer shall draw up a written EU declaration of...
 8. The manufacturer shall, for a period ending 10 years after...
 9. Each notified body shall inform its notifying authorities of quality...
 10. Authorised representative
9. MODULE F: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT VERIFICATION...
1. Conformity to type based on pressure equipment verification is the...
 2. Manufacturing
 3. Verification
 4. Verification of conformity by examination and testing of every item...
 - 4.1. All pressure equipment shall be individually examined and appropriate tests...
 - 4.2. The notified body shall issue a certificate of conformity in...
 5. CE marking and EU declaration of conformity
 - 5.1. The manufacturer shall affix the CE marking and, under the...
 - 5.2. The manufacturer shall draw up a written EU declaration of...
 6. If the notified body agrees and under its responsibility, the...
 7. Authorised representative
10. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION
1. Conformity based on unit verification is the conformity assessment procedure...
 2. Technical documentation
 3. Manufacturing
 4. Verification
 5. CE marking and EU declaration of conformity
 - 5.1. The manufacturer shall affix the CE marking and, under the...
 - 5.2. The manufacturer shall draw up a written EU declaration of...
 6. Authorised representative
11. MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE
1. Conformity based on full quality assurance is the conformity assessment...
 2. Manufacturing
 3. Quality system
 - 3.1. The manufacturer shall lodge an application for assessment of his...
 - 3.2. The quality system shall ensure compliance of the pressure equipment...
 - 3.3. The notified body shall assess the quality system to determine...
 - 3.4. The manufacturer shall undertake to fulfil the obligations arising out...
 - 3.5. The manufacturer shall keep the notified body that has approved...
 4. Surveillance under the responsibility of the notified body
 - 4.1. The purpose of surveillance is to make sure that the...
 - 4.2. The manufacturer shall, for assessment purposes, allow the notified body...
 - 4.3. The notified body shall carry out periodic audits to make...
 - 4.4. In addition, the notified body may pay unexpected visits to...
 5. CE marking and EU declaration of conformity
 - 5.1. The manufacturer shall affix the CE marking and, under the...
 - 5.2. The manufacturer shall draw up a written EU declaration of...
 6. The manufacturer shall, for a period ending 10 years after...
 7. Each notified body shall inform its notifying authorities of quality...

8. Authorised representative
12. MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN...
 1. Conformity based on full quality assurance plus design examination and...
 2. Manufacturing
 3. Quality system
 - 3.1. The manufacturer shall lodge an application for assessment of his...
 - 3.2. The quality system shall ensure compliance of the pressure equipment...
 - 3.3. The notified body shall assess the quality system to determine...
 - 3.4. The manufacturer shall undertake to fulfil the obligations arising out...
 - 3.5. The manufacturer shall keep the notified body that has approved...
 - 3.6. Each notified body shall inform its notifying authorities of quality...
 4. Design examination
 - 4.1. The manufacturer shall lodge an application for examination of the...
 - 4.2. The application shall make it possible to understand the design,...
 - 4.3. The notified body shall examine the application, and where the...
 - 4.4. The notified body shall keep itself apprised of any changes...
 - 4.5. Each notified body shall inform its notifying authorities of the...
 - 4.6. The manufacturer shall keep a copy of the EU design...
 5. Surveillance under the responsibility of the notified body
 - 5.1. The purpose of surveillance is to make sure that the...
 - 5.2. The manufacturer shall, for assessment purposes, allow the notified body...
 - 5.3. The notified body shall carry out periodic audits to make...
 - 5.4. In addition, the notified body may pay unexpected visits to...
 - 5.5. Special surveillance of the final assessment
 6. CE marking and EU declaration of conformity
 - 6.1. The manufacturer shall affix the CE marking and, under the...
 - 6.2. The manufacturer shall draw up a written EU declaration of...
 7. The manufacturer shall, for a period ending 10 years after...
 8. Authorised representative

ANNEX IV

EU DECLARATION OF CONFORMITY (No XXXX)

1. Pressure equipment or assembly (product, type, batch or serial number):...
2. Name and address of the manufacturer and, where applicable, his...
3. This declaration of conformity is issued under the sole responsibility...
4. Object of the declaration (identification of pressure equipment or assembly...
5. The object of the declaration described above is in conformity...
6. References to the relevant harmonised standards used or references to...
7. Where appropriate, the name, address and number of the notified...

8. Additional information:

ANNEX V

ANNEX VI

Signature

- (1) [OJ C 67, 6.3.2014, p. 101.](#)
- (2) Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and decision of the Council of 13 May 2014.
- (3) Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment ([OJ L 181, 9.7.1997, p. 1.](#)).
- (4) See Annex V, Part A.
- (5) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ([OJ L 218, 13.8.2008, p. 30.](#)).
- (6) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC ([OJ L 218, 13.8.2008, p. 82.](#)).
- (7) Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods ([OJ L 260, 30.9.2008, p. 13.](#)).
- (8) Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC ([OJ L 165, 30.6.2010, p. 1.](#)).
- (9) Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([OJ 196, 16.8.1967, p. 1.](#)).
- (10) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ([OJ L 353, 31.12.2008, p. 1.](#)).
- (11) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([OJ L 316, 14.11.2012, p. 12.](#)).
- (12) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13.](#)).