

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 2

### OBLIGATIONS OF ECONOMIC OPERATORS

#### *Article 6*

##### **Obligations of manufacturers**

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.

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.

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.

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.

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.

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.

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.

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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.

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.

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.

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.

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.

## *Article 7*

### **Authorised representatives**

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.

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:

- 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;

- 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;
- 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.

### *Article 8*

#### **Obligations of importers**

1 Importers shall place only compliant pressure equipment or assemblies on the market.

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).

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).

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.

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.

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.

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.

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.

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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.

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.

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.

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.

### *Article 9*

#### **Obligations of distributors**

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.

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.

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.

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.

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.

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.

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.

#### *Article 10*

##### **Cases in which obligations of manufacturers apply to importers and distributors**

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.

#### *Article 11*

##### **Identification of economic operators**

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with pressure equipment or an assembly;
- (b) any economic operator to whom they have supplied pressure equipment or an assembly.

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.