

---

## STATUTORY INSTRUMENTS

---

# 2016 No. 1105

## The Pressure Equipment (Safety) Regulations 2016

### PART 2

#### Obligations of economic operators

##### Manufacturers

#### **Design and manufacture in accordance with essential safety requirements**

**9.**—(1) Before placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market or using it for their own purposes, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential safety requirements.

(2) Before placing pressure equipment or an assembly referred to in regulation 8 on the market or using it for their own purposes, a manufacturer must ensure that it complies with regulation 8(2).

#### **Technical documentation and conformity assessment**

**10.**—(1) Before placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market or using it for their own purposes, a manufacturer must—

- (a) classify it using the categories set out in Schedule 3 (classification of pressure equipment), according to an ascending level of hazard;
- (b) determine the conformity assessment procedures to apply to the pressure equipment or assembly in accordance with regulation 41 (conformity assessment procedure);
- (c) carry out the relevant conformity assessment procedure in respect of that pressure equipment or assembly, or have such a procedure carried out; and
- (d) draw up the relevant technical documentation referred to in the conformity assessment module followed in accordance with regulation 41.

(2) For the purposes of paragraph (1)(d), the relevant technical documentation is the following with reference to the modules set out in Annex III to the Directive (as amended from time to time)—

- (a) where Module A is followed, the technical documentation is the technical documentation referred to in point 2 under Module A (Internal production control);
- (b) where Module A2 is followed, the technical documentation is the technical documentation referred to in point 2 under Module A2 (Internal production control plus supervised pressure equipment checks at random intervals);
- (c) where Module B (production type) is followed, the technical documentation is the technical documentation referred to in point 3 under Module B (EU-type examination – production type);
- (d) where Module B (design type) is followed, the technical documentation is the technical documentation referred to in point 3 under Module B (EU-type examination – design type);
- (e) where Module G is followed, the technical documentation is the technical documentation referred to in point 2 under Module G (Conformity based on unit verification);

- (f) where Module H is followed, the technical documentation is the technical documentation referred to in point 3 under Module H (Conformity based on full quality assurance);
- (g) where Module H1 is followed, the technical documentation is the technical documentation referred to in point 3 under Module H1 (Conformity based on full quality assurance plus design examination).

### **EU declaration of conformity and CE marking**

**11.**—(1) Where the conformity of pressure equipment or an assembly referred to in regulation 6 or 7 with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the pressure equipment or assembly on the market—

- (a) draw up a declaration of conformity in accordance with regulation 48 (EU declaration of conformity);
  - (b) affix the CE marking in accordance with regulation 49 (CE marking); and
  - (c) where applicable, ensure that the identification number of the notified body is affixed in accordance with regulation 49.
- (2) The requirement in paragraph (1)(b) does not apply in cases where—
- (a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and
  - (b) the conformity assessment procedure has been carried out by a user inspectorate.
- (3) The manufacturer must keep the EU declaration of conformity up-to-date.
- (4) Where pressure equipment or an assembly is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity which—
- (a) identifies the EU instruments; and
  - (b) includes references to the publication of those EU instruments in the Official Journal.

### **Duty to keep technical documentation and EU declaration of conformity**

**12.** A manufacturer must keep the technical documentation and the EU declaration of conformity drawn up in respect of pressure equipment or an assembly and make them available for inspection by the enforcing authorities for a period of 10 years beginning on the day on which the pressure equipment or assembly is placed on the market.

### **Labelling of pressure equipment and assemblies**

**13.**—(1) Before placing pressure equipment or an assembly on the market, a manufacturer must—

- (a) ensure that it bears a type, batch or serial number or other element allowing its identification; and
- (b) ensure that it is marked with—
  - (i) the name, registered trade name or registered trade mark of the manufacturer; and
  - (ii) a single postal address at which the manufacturer can be contacted.

(2) Where it is not possible for information specified in paragraph (1)(a) and (b) to be indicated on the pressure equipment or assembly, the manufacturer must ensure that the information is indicated on its packaging or in a document accompanying the pressure equipment or assembly.

(3) The details set out in paragraph (1)(b) must be in a language which can be easily understood by consumers, other users and market surveillance authorities in the member State in which it is to be made available to such users.

### **Instructions and safety information**

**14.**—(1) When placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, a manufacturer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users.

(2) The instructions and safety information referred to in paragraph (1) must include the information listed in paragraphs 29 and 30 of Schedule 2.

(3) When placing pressure equipment or an assembly covered by regulation 8 on the market, a manufacturer must ensure that it is accompanied by adequate instructions for use in a language which can be easily understood by consumers and other users.

(4) Where the pressure equipment or assembly is placed on the market in the United Kingdom, the language referred to in paragraphs (1) and (3) must be English.

(5) Instructions and safety information must be clear, understandable and intelligible.

### **Compliance procedures for series production**

**15.**—(1) A manufacturer of pressure equipment or assemblies which are manufactured by series production must ensure that procedures are in place to ensure that any pressure equipment or assemblies so manufactured will be in conformity with Part 2.

(2) In doing so, the manufacturer must take adequate account of—

- (a) any change in pressure equipment or assembly design or characteristics; and
- (b) any change in a harmonised standard or in another technical specification by reference to which the EU declaration of conformity was drawn up.

### **Monitoring**

**16.**—(1) When appropriate, with regard to the risks to the health and safety of consumers and other users presented by pressure equipment or assemblies, the manufacturer must—

- (a) carry out sample testing of pressure equipment or assemblies made available on the market;
- (b) investigate complaints that pressure equipment or assemblies are not in conformity with Part 2;
- (c) keep a register of—
  - (i) complaints that pressure equipment or assemblies are not in conformity with Part 2;
  - (ii) pressure equipment or assemblies which are found not to be in conformity with Part 2; and
  - (iii) pressure equipment or assemblies recalls; and
- (d) keep distributors informed of any monitoring carried out under this regulation.

(2) The manufacturer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

**Duty to take action in respect of pressure equipment or assemblies placed on the market which are considered not to be in conformity**

17.—(1) A manufacturer who considers, or has reason to believe, that pressure equipment or an assembly which that manufacturer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

- (a) bring the pressure equipment or assembly into conformity;
- (b) withdraw the pressure equipment or assembly; or
- (c) recall the pressure equipment or assembly.

(2) Where pressure equipment or an assembly presents a risk, the manufacturer must immediately inform the market surveillance authority, and the competent national authorities of any other member State in which the manufacturer made the pressure equipment or assembly available on the market, of the risk, giving details of—

- (a) the respect in which the pressure equipment or assembly is considered not to be in conformity with Part 2; and
- (b) any corrective measures taken.

**Provision of information and cooperation**

18.—(1) Further to a request from an enforcing authority, and within such period as the authority may specify, a manufacturer must provide the authority with all the information and documentation necessary to demonstrate that pressure equipment or an assembly is in conformity with Part 2.

(2) A request referred to in paragraph (1)—

- (a) may only be made during the period of 10 years beginning on the day the pressure equipment or assembly was placed on the market; and
- (b) must be accompanied by the reasons for making the request.

(3) The information and documentation referred to in paragraph (1)—

- (a) may be provided electronically; and
- (b) must be in a language which can be easily understood by the enforcing authority.

(4) A manufacturer must, at the request of the enforcing authority, cooperate with that authority on any action taken to—

- (a) evaluate pressure equipment or an assembly in accordance with regulation 70 (evaluation of pressure equipment or assemblies presenting a risk); or
- (b) eliminate the risks posed by pressure equipment or an assembly which the manufacturer has placed on the market.

**Manufacturer's authorised representatives**

19.—(1) A manufacturer may, by written mandate, appoint a person as their authorised representative to perform specified tasks on the manufacturer's behalf.

(2) The mandate must allow the authorised representative to do at least the following in relation to pressure equipment or assemblies covered by the mandate—

- (a) perform the manufacturer's obligations under regulation 12 (duty to keep technical documentation and EU declaration of conformity); and
- (b) perform the manufacturer's obligations under regulation 18 (provision of information and cooperation).

(3) The obligations laid down in regulation 9 (design and manufacture in accordance with the essential safety requirements) and regulation 10(1)(b) (technical documentation and conformity assessment) must not form part of an authorised representative's mandate.

(4) An authorised representative must comply with all the duties imposed on the manufacturer in relation to each obligation under these Regulations that the representative is appointed by the manufacturer to perform and, accordingly as far as those duties, as well as the penalties for failure to comply with those duties, are concerned, references in these Regulations (except in this regulation) to the manufacturer are to be taken as including a reference to the authorised representative.

(5) A manufacturer who has appointed an authorised representative to perform on the manufacturer's behalf an obligation under these Regulations remains responsible for the proper performance of that obligation.

### Importers

#### **Prohibition on placing on the market pressure equipment or assemblies which are not in conformity**

**20.** An importer must not place pressure equipment or an assembly on the market unless it is in conformity with Part 2.

#### **Requirements which must be satisfied before an importer places pressure equipment or assemblies on the market**

**21.—**(1) Before placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, an importer must ensure that—

- (a) the relevant conformity assessment procedure has been carried out;
- (b) the manufacturer has drawn up the technical documentation;
- (c) the pressure equipment or assembly—
  - (i) bears the CE marking; and
  - (ii) is accompanied by the required documents; and
- (d) the manufacturer has complied with the requirements of regulation 13 (labelling).

(2) The requirement in paragraph (1)(c)(i) does not apply in cases where—

- (a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and
- (b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) Before placing pressure equipment or an assembly referred to in regulation 8 on the market, an importer must ensure that—

- (a) the manufacturer has drawn up the technical documentation;
- (b) the pressure equipment or assembly is accompanied by adequate instructions for use and any required documents; and
- (c) the manufacturer has complied with the requirements of regulation 13 (labelling).

(4) In paragraphs (1)(c)(ii) and (3)(b), “required documents” means any documents that the manufacturer is required to provide with pressure equipment or an assembly pursuant to regulation 13(2) (labelling) and 14 (instructions and safety information).

**Prohibition on placing on the market pressure equipment or assemblies considered not to be in conformity with the essential safety requirements**

22.—(1) Where an importer considers, or has reason to believe, that pressure equipment or an assembly referred to in Regulation 6 or 7 is not in conformity with the essential safety requirements, the importer must not place the pressure equipment or assembly on the market.

(2) Where pressure equipment or an assembly presents a risk, the importer must inform the manufacturer and the market surveillance authority of that risk.

**Information identifying importer**

23.—(1) Before placing pressure equipment or an assembly on the market, an importer must indicate on the pressure equipment or assembly—

- (a) the name, registered trade name or registered trade mark of the importer; and
- (b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) must be in a language which can be easily understood by consumers and other users and the market surveillance authority in the member State in which it is to be made available to such users.

(3) Where it is not possible to indicate the information specified in paragraph (1) on pressure equipment, the importer must indicate that information—

- (a) on the packaging; or
- (b) in a document accompanying the pressure equipment or assembly.

**Instructions and safety information**

24.—(1) When placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, an importer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users.

(2) The instructions and safety information referred to in paragraph (1) must include the information listed in paragraphs 29 and 30 of Schedule 2.

(3) When placing pressure equipment or an assembly covered by regulation 8 on the market, an importer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users.

(4) Where the pressure equipment or assembly is placed on the market in the United Kingdom, the language referred to in paragraphs (1) and (3) must be English.

**Storage and transport**

25. Where an importer has responsibility for pressure equipment or an assembly referred to in Regulation 6 or 7, the importer must ensure that the conditions under which the pressure equipment or assembly is stored or transported do not jeopardise its conformity with the essential safety requirements.

**Monitoring**

26.—(1) Where appropriate, having regard to the risks to the health and safety of consumers and other users presented by the pressure equipment or assemblies, the importer must—

- (a) carry out sample testing of pressure equipment and assemblies made available on the market by the importer;

- (b) investigate complaints of pressure equipment and assemblies made available on the market by the importer which are not in conformity with Part 2;
  - (c) keep a register of—
    - (i) complaints that pressure equipment or assemblies are not in conformity with Part 2;
    - (ii) pressure equipment or assemblies which are found not to be in conformity with Part 2; and
    - (iii) pressure equipment or assemblies recalls; and
  - (d) keep distributors informed of any monitoring carried out under this regulation.
- (2) The importer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

**Duty to take action in respect of pressure equipment or assemblies placed on the market considered not to be in conformity**

**27.**—(1) An importer who considers, or has reason to believe, that pressure equipment or an assembly which that importer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

- (a) bring that pressure equipment or assembly into conformity;
- (b) withdraw the pressure equipment or assembly; or
- (c) recall the pressure equipment or assembly.

(2) Where the pressure equipment or assembly presents a risk, the importer must immediately inform the market surveillance authority and the competent national authorities of any other member State in which the importer made the pressure equipment or assembly available on the market of the risk, giving details of—

- (a) the respect in which the pressure equipment or assembly is considered not to be in conformity with Part 2; and
- (b) any corrective measures taken.

**Retention of technical documentation and EU declaration of conformity**

**28.** An importer must, for a period of 10 years beginning on the day on which pressure equipment or an assembly is placed on the market, keep and, upon request, make available to an enforcing authority the following in relation to the pressure equipment or assembly—

- (a) a copy of the EU declaration of conformity; and
- (b) the technical documentation.

**Provision of information and cooperation**

**29.**—(1) Following a request from an enforcing authority, and within such period as the authority may specify, an importer must provide the authority with all the information and documentation necessary to demonstrate that pressure equipment or an assembly is in conformity with Part 2.

(2) A request referred to in paragraph (1)—

- (a) may only be made during the period of 10 years beginning on the day the importer places the pressure equipment or assembly on the market; and
- (b) must be accompanied by the reasons for making the request.

(3) The information and documentation referred to in paragraph (1)—

- (a) may be provided electronically; and

- (b) must be in a language which can be easily understood by the enforcing authority.
- (4) An importer must, at the request of the enforcing authority, cooperate with that authority on any action taken to—
  - (a) evaluate pressure equipment or assemblies in accordance with regulation 70 (evaluation of pressure equipment or assemblies presenting a risk); or
  - (b) eliminate the risks posed by pressure equipment or assemblies which the importer has placed on the market.

#### Distributors

#### **Duty to act with due care**

**30.** When making pressure equipment or an assembly available on the market, a distributor must act with due care to ensure that it is in conformity with Part 2.

#### **Requirements which must be satisfied before a distributor makes pressure equipment or assemblies available on the market)**

**31.**—(1) Before making pressure equipment or an assembly referred to in regulation 6 or 7 available on the market, the distributor must verify that—

- (a) the pressure equipment or assembly—
  - (i) bears the CE marking;
  - (ii) is accompanied by the required documents;
  - (iii) the instructions and safety information are 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;
- (b) the manufacturer has complied with the requirements of regulation 13 (labelling of pressure equipment and assemblies); and
- (c) the importer has complied with the requirements of regulation 23 (information identifying importer).

(2) In paragraph (1)(a)(ii), “required documents” means the documents that the manufacturer or importer is required to provide with pressure equipment or assemblies pursuant to—

- (a) regulation 13 (labelling of pressure equipment and assemblies);
- (b) regulation 23 (information identifying importer);
- (c) regulation 14 or 24 (instructions and safety information); and
- (d) regulation 49 (CE marking).

(3) Where the pressure equipment or assembly is made available on the market in the United Kingdom, the language referred to in paragraph (1)(a)(iii) must be English.

#### **Storage and transport**

**32.** Where a distributor has responsibility for pressure equipment or an assembly referred to in Regulation 6 or 7, the distributor must ensure that the conditions under which the pressure equipment or assembly is stored or transported do not jeopardise its conformity with the essential safety requirements.



**Prohibition on making available on the market where pressure equipment or assemblies are not considered to be in conformity with essential safety requirements**

**33.**—(1) Where a distributor considers, or has reason to believe, that pressure equipment or an assembly referred to in Regulation 6 or 7 is not in conformity with the essential safety requirements, the distributor must not make the pressure equipment or assembly available on the market until it has been brought into conformity.

(2) Where the pressure equipment or assembly presents a risk, the distributor must inform the following persons of the risk—

- (a) the manufacturer or the importer; and
- (b) the market surveillance authority.

**Duty to take action in respect of pressure equipment made available on the market which are not in conformity**

**34.**—(1) A distributor who considers, or has reason to believe, that pressure equipment or assemblies which the distributor has made available on the market is not in conformity with Part 2 must make sure that the necessary corrective measures are taken to—

- (a) bring that pressure equipment or assembly into conformity;
- (b) withdraw the pressure equipment or assembly; or
- (c) recall the pressure equipment or assembly.

(2) Where the pressure equipment or assembly presents a risk, the distributor must immediately inform the market surveillance authority, and the competent national authorities of the member States in which the distributor has made the pressure equipment or assembly available on the market, of that risk, giving details of—

- (a) the respect in which pressure equipment is considered not to be in conformity with Part 2; and
- (b) any corrective measures taken.

**Provision of information and cooperation**

**35.**—(1) Following a request from an enforcing authority, and within such period as the authority may specify, a distributor must provide the authority with all the information and documentation necessary to demonstrate that pressure equipment or an assembly is in conformity with Part 2.

(2) The information referred to in paragraph (1)—

- (a) may be provided electronically; and
- (b) must be in a language which can be easily understood by the enforcing authority.

(3) A distributor must, at the request of the enforcing authority, cooperate with that authority on any action taken to—

- (a) evaluate pressure equipment in accordance with regulation 70 (evaluation of pressure equipment or assemblies presenting a risk); or
- (b) eliminate the risks posed by pressure equipment or assemblies which the distributor has made available on the market.

## All economic operators

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

**36.** An importer or distributor (“A”) is to be considered a manufacturer for the purposes of these Regulations, and is subject to the obligations of the manufacturer under this Part, where A—

- (a) places pressure equipment or an assembly on the market under A’s own name or trademark; or
- (b) modifies pressure equipment or an assembly already placed on the market in such a way that it may affect whether the pressure equipment or assembly is in conformity with Part 2.

### Translation of EU declaration of conformity

**37.**—(1) Before making pressure equipment or an assembly available on the market, an economic operator must ensure that the EU declaration of conformity is prepared in, or translated into, the language required by the member State in which it is to be made available on the market.

(2) Where the pressure equipment or assembly is to be made available on the market in the United Kingdom, the language required is English.

### Identification of economic operators

**38.**—(1) An economic operator (“E”) who receives a request in relation to pressure equipment or an assembly from the market surveillance authority before the end of the relevant period must, within such period as that authority may specify, identify to the authority—

- (a) any other economic operator who has supplied E with the pressure equipment or assembly; and
  - (b) any other economic operator to whom E has supplied the pressure equipment or assembly.
- (2) The relevant period is—
- (a) for information under paragraph (1)(a), 10 years beginning on the day on which E was supplied with the pressure equipment or assembly; and
  - (b) for information under paragraph (1)(b), 10 years beginning on the day on which E supplied the pressure equipment or assembly.

### Prohibition on improper use of CE marking

**39.**—(1) An economic operator must not affix the CE marking to pressure equipment or an assembly unless—

- (a) that economic operator is the manufacturer of the pressure equipment or assembly; and
  - (b) the conformity of the pressure equipment or assembly with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure.
- (2) An economic operator must not affix the CE marking to pressure equipment or an assembly where—
- (a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and
  - (b) the conformity assessment procedure has been carried out by a user inspectorate.
- (3) An economic operator must not affix to pressure equipment or an assembly a marking which—
- (a) is not the CE marking; but

- (b) purports to attest that the pressure equipment or assembly is in conformity with the essential safety requirements.
- (4) An economic operator must not affix to pressure equipment or an assembly a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking.
- (5) An economic operator must not affix to pressure equipment or an assembly any other marking if the visibility, legibility and meaning of the CE marking would be impaired as a result.