STATUTORY INSTRUMENTS.

S.I. No. 233 of 2017

EUROPEAN UNION (PRESSURE EQUIPMENT) REGULATIONS 2017

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EUROPEAN UNION (PRESSURE EQUIPMENT) REGULATIONS 2017

I, MARY MITCHELL O'CONNOR, Minister for Jobs, Enterprise and Innovation, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) (as amended by section 2 of the European Communities Act 2007) (No. 18 of 2007)) and for the purpose of giving effect to Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014[1] and of giving further effect to Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008[2], hereby make the following regulations:

PART 1

CITATION, INTERPRETATION

Citation

1. These Regulations may be cited as the European Union (Pressure Equipment) Regulations 2017.

Interpretation

2. (1) In these Regulations—

"accreditation" has the meaning assigned to it in point 10 of Article 2 of Regulation (EC) No. 765/2008;

"Act of 2005" means the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005);

"assemblies" means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;

"authorised representative" means any natural or legal person established within the European Economic Area who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

"CE marking" means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

"Companies Acts" means the Companies Act 2014 (No. 38 of 2014) or, as the context may require, the legislation repealed by s. 4 of the Companies Act 2014;

"competent authority" means—

[1]OJ No. L189, 27.06.2014, p. 164.
[2]OJ No. L. 218, 13.8.2008, p. 30.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 2*nd June*, 2017.

(*a*) in the State, the market surveillance authority, or

(*b*) in another Member State, any authority or body to whom functions have been assigned as a competent authority or a market surveillance authority, for the purposes of the Directive;

"conformity assessment" means the process demonstrating whether the essential safety requirements of the Directive or these Regulations relating to a product have been fulfilled;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection and includes notified bodies, recognised third-party organisations or user inspectorates;

"contravention notice" means the notice provided for in Regulation 38;

"Coroners Acts 1962 and 2005" means the Coroners Act 1962 (No. 9 of 1962) as amended by the Coroners (Amendment) Act 2005 (No. 33 of 2005);

"Directive" means Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014;

"Directive 97/23/EC" means Directive 97/23/EC of the European Parliament and of the council of 29 May 1997[3];

"distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

"economic operator" means a manufacturer, authorised representative, importer or distributor;

"EU declaration of conformity" means a declaration of conformity drawn up in accordance with Regulation 19;

"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;

"fluids" means gases, liquids and vapours in pure phase as well as mixtures thereof and fluids may contain a suspension of solids;

"harmonised standard" means harmonised standard as defined in point (*c*) of Point 1 of Article 2 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012[4];

"importer" means any natural or legal person established within the European Economic Area who places a product from a third country on the market of the European Economic Area;

[3]OJ No. L 181, 9.7.97, p.1.
[4]OJ No. L 316, 14.11.2012, p.12.

"information notice" means the notice provided for in Regulation 43;

"inspector" has the meaning assigned to it in Regulation 35(2);

"Irish National Accreditation Board" means the national body with responsibility for the accreditation of laboratories, certification bodies and inspection bodies, and notified to the European Commission as being the sole accreditation body for Ireland in line with Regulation (EC) No 765/2008;

"making available on the market" means any supply of a product for distribution or use on the market of the European Economic Area in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark or uses it for his own purposes;

"market surveillance authority" means the authority designated as a market surveillance authority under Regulation 3;

"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;

"maximum/minimum allowable temperature TS" means the maximum/minimum temperatures for which the equipment is designed, as specified by the manufacturer;

"Member State" means a state which is a contracting party to the Agreement on the European Economic Area signed in Oporto on 2 May 1992;

"Minister" means the Minister for Jobs, Enterprise and Innovation;

"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;

"notified body" means—

(*a*) in the State, a body authorised to carry out conformity assessment tasks in accordance with Articles 14 and 15 of the Directive and Regulations 15 and 16 of these Regulations and notified by the notifying authority pursuant to Regulation 22;

(*b*) in another Member State, a body authorised to carry out conformity assessment tasks in accordance with Articles 14 and 15 of the

Directive and notified by the relevant notifying authority pursuant to the Directive;

"notifying authority" means the authority designated as the notifying authority in the State under Regulation 3 and in another Member State the authority designated as notifying authority pursuant to the Directive;

"Official Journal" means the Official Journal of the European Union;

"permanent joints" means joints which cannot be disconnected except by destructive methods;

"person in charge" means, in relation to a place—

(*a*) the person under whose direction and control the activities at that place are being conducted, or

(*b*) the person whom the inspector has reasonable grounds for believing is in control of that place;

"piping" means piping components intended for the transport of fluids, when connected together for integration into a pressure system and 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;

"placing on the market" means the first making available of a product on the market of the European Economic Area;

"premises of an economic operator" means any premises owned or being used by an economic operator;

"pressure" means pressure relative to atmospheric pressure, i.e. gauge pressure and, as a consequence, vacuum is designated by a negative value;

"pressure accessories" means devices with an operational function and having pressure-bearing housings;

"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;

"product" means the items specified in Regulation 4(1);

"prohibition notice" means the notice provided for in Regulation 40;

"putting into service" means the first use of a product by its user;

"recall" means any measure aimed at achieving the return of a product that have already been made available to consumers or other users;

"Regulation (EC) No. 765/2008" means 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. 996/93;

"Regulations of 1999" means the European Communities (Pressure Equipment) Regulations (S.I. No. 400 of 1999);

"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;

"technical specification" means a document that prescribes technical requirements to be fulfilled by a product;

" recognised third-party organisation" means—

(*a*) in the State, a body recognised by the notifying authority for the purposes of the tasks referred to in points 3.1.2 and 3.1.3 of Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations and notified by the notifying authority in accordance with Regulation 22;

(*b*) in another Member State, a body recognised by the notifying authority for the purposes of the tasks referred to in points 3.1.2 and 3.1.3 of Annex I to the Directive and notified by that authority pursuant to the Directive;

"Union harmonisation legislation" means any European Union legislation harmonising the conditions for the marketing of products.

"user inspectorate" means—

(*a*) in the State, a body authorised to carry out conformity assessment tasks in accordance with Article 16 of the Directive and Regulation 17 of these Regulations and notified by the notifying authority pursuant to Regulation 22;

(*b*) in another Member State, a body authorised to carry out conformity assessment tasks in accordance with Article 16 of the Directive and notified by the relevant notifying authority pursuant to the Directive;

"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 and a vessel may be composed of more than one chamber;

"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;

"withdrawal" means any measure aimed at preventing a product in the supply chain from being made available on the market;

(2) A word or expression which is used in these Regulations and which is also used in the Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive.

(3) References to the repealed Directive 97/23/EC shall be construed in existing laws, regulations and administrative provisions of the State as references to the Directive and shall be read in accordance with the correlation table in Annex VI to the Directive, the text of which is set out in Schedule 5 to these Regulations.

Designation

3. For the purposes of the Directive and these Regulations—

(*a*) the Health and Safety Authority is designated as the market surveillance authority, and

(*b*) the Minister is designated as the notifying authority.

Application

4. (1) Subject to paragraph (2), these Regulations apply to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar.

(2) These Regulations do not apply to the equipment and items referred to in Article 1(2) of the Directive.

Making available on the market and putting into service

5. (1) Subject to paragraph (2), a person shall not make available on the market or put into service a product unless it satisfies the requirements of the Directive or these Regulations when properly installed and maintained and used for the purpose for which it is intended.

(2) Paragraph (1) shall not prevent a person from showing a product which does not comply with the Directive or these Regulations at a trade fair, exhibition, demonstration provided that—

(*a*) a visible sign clearly indicates that the product does not comply with the Directive or these Regulations and that it will not be made available on the market or put into service until it has been brought into conformity, and

(*b*) appropriate safety measures are taken during demonstrations to ensure the protection of persons.

Essential safety requirements

6. (1) Subject to paragraph (4), pressure equipment listed in Article 4(1)(*a*) to 4(1)(*d*) of the Directive shall satisfy the essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations.

(2) Subject to paragraphs (3) and (4), assemblies which include at least one item of pressure equipment covered by paragraph (1) and listed in Article 4(2)(*a*) and 4(2)(*b*) of the Directive shall satisfy the essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations.

(3) 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 to the Directive, the text of which is set out in Schedule 1 to these Regulations.

(4) Pressure equipment and assemblies, below or equal to the limits set out in Article 4(1) (*a*), (*b*) and (*c*) and Article 4(2) to the Directive respectively, shall be designed and manufactured in accordance with sound engineering practice in a Member State in order to ensure safe use and accompanied by adequate instructions for use but, subject 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 of the Directive.

PART 2

OBLIGATIONS OF ECONOMIC OPERATORS

Obligations of manufacturers

7. A manufacturer shall—

(*a*) subject to Regulation 6(3), ensure that when placing the pressure equipment or assemblies referred to in Regulation 6(1), (2) or (3) on the market or when using same for the manufacturer's own purposes, that that equipment or those assemblies have been designed and manufactured in accordance with the essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations,

(*b*) ensure that when placing the pressure equipment or assemblies referred to in Regulation 6(4) on the market or when using same for the manufacturer's own purposes, that that equipment or those assemblies have been designed and manufactured in accordance with sound engineering practice in a Member State,

(*c*) in the case of pressure equipment or assemblies referred to in Regulation 6(1), (2) or (3), draw up the technical documentation referred to in Annex III, the text of which is set out at Schedule III to these

Regulations, and carry out the relevant conformity assessment procedure referred to in Regulation 15 or have it carried out,

(*d*) in a case where compliance of pressure equipment or assemblies referred to in Regulation 6(1), (2) or (3) with the applicable requirements has been demonstrated by the conformity assessment procedure carried out under paragraph (*c*)—

(i) draw up an EU declaration of conformity in accordance with Regulation 19, and

(ii) affix the CE marking in accordance with Regulation 21,

(*e*) retain the technical documentation and the EU declaration of conformity for 10 years after the pressure equipment or assemblies have been placed on the market,

(*f*) ensure that procedures are in place for series production to remain in conformity with the Directive or these Regulations and that 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, are adequately taken into account,

(*g*) in a case where it is deemed appropriate by the market surveillance authority, with regard to the risks presented by pressure equipment or assemblies and in order to protect the health and safety of consumers and other users—

(i) carry out sample testing of pressure equipment or assemblies made available on the market,

(ii) investigate and keep a register of complaints of non-conforming pressure equipment and assemblies and recalls of such equipment, and

(iii) keep distributors informed of any such monitoring,

(*h*) ensure that pressure equipment or assemblies which it has placed on the market 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 or assembly,

(*i*) indicate on the pressure equipment or assembly in a language easily understood by consumers, other users and the competent authorities, the manufacturer's name, registered trade name or registered trade mark and the postal address at which they can be contacted, which address shall indicate a single point of contact or, where that is not

possible, on the packaging or in a document accompanying the equipment or assembly,

(*j*) ensure that the pressure equipment or assembly referred to in Regulation 6(1), (2) and (3) is accompanied by instructions and safety information in accordance with point 3.4 of Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations and in the case of the equipment or assemblies referred to in Regulation 6(1) or (2), also accompanied by instructions and safety information in accordance with point 3.3 of Annex I to the Directive, in a language easily understood by consumers and other users and that such instructions and safety information are clear, understandable and intelligible,

(*k*) ensure that the pressure equipment or assembly referred to in Regulation 6(4) which it has placed on the market are accompanied by instructions and safety information in accordance with Regulation 6(4) in a language easily understood by consumers and other users and that such instructions and safety information are clear, understandable and intelligible,

(*l*) in the case of pressure equipment or an assembly which the manufacturer has placed on the market and which the manufacturer considers or has reason to believe is not in conformity with the Directive or these Regulations—

(i) immediately take the corrective measures necessary to bring that equipment or those assemblies into conformity, to withdraw it or recall it if appropriate, and

(ii) where any pressure equipment or assembly presents a risk, immediately inform the competent authorities of the Member States in which the manufacturer made the product available on the market, giving details, in particular, of the non-compliance and of any corrective measures taken,

and

(*m*) further to a reasoned request from a competent authority in respect of a product which the manufacturer has made available on the market—

(i) provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the pressure equipment or assembly with the Directive or these Regulations, in a language which can be easily understood by that authority, and

(ii) cooperate with that authority, at its request, on any action taken to eliminate the risks posed by any pressure equipment or assembly placed on the market by the manufacturer.

Authorised representatives

8. (1) A manufacturer may, by a written mandate, appoint an authorised representative for the purposes of the Directive or these Regulations.

(2) The obligations laid down in Regulation 7(*a*), (*b*) and the obligation to draw up technical documentation under Regulation 7(*c*) shall not form part of the mandate of an authorised representative appointed under paragraph (1).

(3) An authorised representative appointed under paragraph (1) shall perform the tasks specified in the mandate received from the manufacturer which shall, at least, allow the authorised representative to—

(*a*) keep the EU declaration of conformity and the technical documentation at the disposal of competent 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 authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly, and

(*c*) cooperate with a competent authority, at its request, on any action taken to eliminate the risks posed by pressure equipment or assemblies covered by the authorised representative's mandate.

Obligations of importers

9. (1) An importer shall not place pressure equipment or assemblies on the market unless they comply with the Directive and these Regulations.

(2) An importer shall—

(*a*) before placing any pressure equipment or assembly referred to in Regulations 6(1), (2) or (3) on the market, ensure that—

(i) the appropriate conformity assessment procedure referred to in Regulation 15, has been carried out by the manufacturer,

(ii) the manufacturer has drawn up the technical documentation,

(iii) the pressure equipment or assembly bears the CE marking,

(iv) the pressure equipment or assembly is accompanied by instructions and safety information in accordance with point 3.4 of Annex I, the text of which is set out in Schedule 1 to these Regulations and in the case of equipment or assemblies referred to in Regulation 6(1) or (2), also accompanied by instructions and safety information in accordance with point 3.3 of Annex I.

(v) the manufacturer has complied with the requirements set out in Regulation 7(*h*) and (*i*),

(*b*) before placing any pressure equipment or assembly referred to in Regulation 6(4) on the market ensure that—

(i) the manufacturer has drawn up the technical documentation,

(ii) they are accompanied by adequate instructions for use, and

(iii) the manufacturer has complied with the requirements set out in Regulation 7(*h*) and (*i*),

(*c*) in a case where the 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 to the Directive, the text of which is set out in Schedule 1 to these Regulations—

(i) not place the pressure equipment or assembly on the market until they have been brought into conformity, and

(ii) where the pressure equipment or assembly presents a risk, inform the manufacturer and the competent authorities of the Member States to that effect,

(*d*) indicate on the pressure equipment or assembly, in a language which can be easily understood by consumers, other users and market surveillance authorities, or where it is not possible to do so on the equipment or assembly, on its packaging or in a document accompanying the equipment or assembly, the importer's name, registered trade name or registered trade mark, and the postal address at which the importer can be contacted,

(*e*) ensure that pressure equipment or assemblies referred to in Regulation 6(1), (2) or (3) are accompanied by instructions and safety information in accordance with point 3.4 of Annex I to the Directive, the text of which is set out in Schedule I to these Regulations and in the case of equipment or assemblies referred to in Regulation 6(1) and (2), also accompanied by instructions and safety information in accordance with point 3.3 of Annex I, in a language which can be easily understood by consumers and other users as determined by the Member State concerned,

(*f*) ensure that pressure equipment or assemblies referred to in Regulation 6(4) are 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,

(*g*) ensure that while pressure equipment or assemblies referred to in Regulation 6(1),(2) or (3) are under the importer's responsibility, their storage or transport conditions do not jeopardise their compliance with the essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule I to these Regulations,

(*h*) in a case where it is deemed appropriate by the market surveillance authority, with regard to the risks presented by pressure equipment or assemblies and in order to protect the health and safety of consumers and other users the importer shall—

(i) carry out sample testing of pressure equipment or assemblies made available on the market,

(ii) investigate and keep a register of complaints, of non-conforming pressure equipment or assemblies and recalls of such equipment, and

(iii) keep distributors informed of any such monitoring,

(*i*) in a case where an importer considers or has reason to believe that pressure equipment or assemblies which the importer has placed on the market are not in conformity with the Directive or these Regulations—

(i) immediately take the corrective measures necessary to bring that pressure equipment or assembly into conformity, to withdraw it or recall it if appropriate, and

(ii) where the pressure equipment or assembly presents a risk, inform the competent authorities of the Member States in which the importer 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,

(*j*) for 10 years after the pressure equipment or assembly has been placed on the market by the importer—

(i) keep a copy of the EU declaration of conformity at the disposal of the competent authorities, and

(ii) ensure that the technical documentation can be made available to those authorities, upon request.

(*k*) further to a reasoned request from a competent authority in respect of a product which the importer has made available on the market—

(i) provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the pressure equipment or assembly, in a language which can be easily understood by that authority, and

(ii) cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the pressure equipment or assembly which the importer has placed on the market.

Obligations of distributors

10. A distributor shall—

(*a*) act with due care in relation to the requirements of the Directive or these Regulations when making a product available on the market,

(*b*) before making the pressure equipment or assemblies referred to in Regulations 6(1),(2) or (3) available on the market, verify that—

(i) the pressure equipment or assembly bears the CE marking,

(ii) the pressure equipment or assembly is accompanied by the required documents and by instructions and safety information in accordance with point 3.4 of Annex I to the Directive, the text of which is set out in Schedule I to these Regulations, and in the case of the equipment or assemblies referred to in Regulation 6(1) and (2), also accompanied by instructions and safety information in accordance with point 3.3 of Annex I, in a language which can be easily understood by consumers and other users in the Member State in which the equipment or assembly is to be made available on the market,

(iii) the manufacturer and the importer have complied with the requirements set out in Regulations 7(*h*) and (i) and Regulation 9(2)(*d*) respectively,

(*c*) in a case where a distributor considers or has reason to believe that any pressure equipment or assembly referred to in Regulation 6(1), (2) or 6(3) are not in conformity with the relevant essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations—

(i) not make the equipment or assembly available on the market until they have been brought into conformity,

(ii) where the equipment or assembly presents a risk, inform the manufacturer or the importer to that effect, as well as the competent authorities of the Member States,

(*d*) before making the pressure equipment or assemblies referred to in Regulation 6(4) available on the market, verify that—

(i) the 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 the equipment or assembly is to be made available on the market, and

(ii) the manufacturer and the importer have complied with the requirements set out in Regulations 7(*h*) and (*i*) and Regulation 9(2)(*d*) respectively,

(*e*) ensure that while the pressure equipment or assemblies referred to in Regulation 6(1), (2) or (3) are the distributor's responsibility, their storage or transport conditions do not jeopardise their compliance with the essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations,

(*f*) in a case where a distributor considers, or has reason to believe, that any product which the distributor has made available on the market is not in conformity with the Directive or these Regulations—

(i) make sure that the corrective measures necessary to bring that pressure equipment or assembly into conformity, to withdraw it or recall it, if appropriate, are taken, and

(ii) where that pressure equipment or assembly presents a risk, immediately inform the competent authorities of the Member States in which the distributor made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken,

(*g*) further to a reasoned request from a competent authority in respect of a product which the distributor has made available on the market—

(i) provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the product, and

(ii) cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the product which the distributor has made available on the market.

Cases in which obligations of manufacturers apply to importers and distributors

11. An importer or distributor shall be considered a manufacturer for the purposes of the Directive or these Regulations and shall be subject to the obligations of the manufacturer under Regulation 7, where that importer or distributor—

(i) places pressure equipment or an assembly on the market under the importer's or distributor's name or trademark, or

(ii) modifies pressure equipment or an assembly already placed on the market in such a way that compliance with the Directive or these Regulations may be affected.

Identification of economic operators

12. (1) An economic operator shall—

(*a*) on request, identify to a competent authority any economic operator—

(i) who has supplied the first named economic operator with a product, or

(ii) to whom the first named operator has supplied a product, and

(*b*) be able to present the information referred to in paragraph (*a*) for 10 years after the first named economic operator has been supplied with, or has supplied, the product.

PART 3

CONFORMITY OF PRODUCTS

Presumption of conformity on the basis of harmonised standards

13. Without prejudice to the powers of the State under Articles 40 and 42 of the Directive—

(*a*) the pressure equipment or assemblies referred to in Regulation 6(1), (2) and (3) which are in conformity with harmonised standards, or parts thereof, the references to which have been published in the Official Journal, shall be presumed to be in conformity with the essential safety requirements covered by those standards or parts thereof, referred to in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations, and

(*b*) 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 in accordance with Article 15(4) of the Directive, shall be presumed to be in conformity with the applicable essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations.

Classification of pressure equipment

14. (1) Subject to paragraphs (2) and (3), pressure equipment referred to in Regulation 6(1) shall be classified by category in accordance with Article 13 of the Directive and Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations, according to an ascending level of hazard and, for the purposes of such classification, fluids shall be divided into two groups in accordance with Article 13(1)(*a*) and (*b*) of the Directive.

(2) Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers.

(3) Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.

Conformity assessment procedures

15. (1) Subject to paragraph (2) before being made available on the market, pressure equipment or assemblies shall be assessed for conformity in accordance with Article 14 of the Directive and the records and correspondence relating to

conformity assessment procedures carried out by a conformity assessment body in the State shall be drafted in English, Irish or in a language accepted by that body.

(2) The market surveillance authority may, where justified, allow individual pressure equipment items and assemblies which have not been subjected to the conformity assessment procedures under paragraph (1) to be made available on the market or put into service if the use to which they will be put is in the interests of experimentation.

European approval for materials

16. (1) Subject to paragraph (2) European approval for materials shall be issued at the request of one or more manufacturers of materials or equipment by one of the bodies notified under Regulation 22 specifically designated for that task but shall not be issued by that body unless the procedure for its issue under Article 15(1) and (2) of the Directive has been complied with.

(2) Where a European approval for materials is issued under paragraph (1), a copy shall be sent to the Member States, the notified bodies and the European Commission.

(3) In a case where a notified body issues a European approval for materials under paragraph (1) but finds that—

(*a*) the approval should not have been issued, or

(*b*) the type of materials is covered by a harmonised standard,

that body shall withdraw that approval and immediately inform the other Member States, the notified bodies and the European Commission of such withdrawal.

User inspectorates

17. (1) The notifying authority may authorise, in the State, 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 appointed under paragraph (2).

(2) For the purposes of paragraph (1), the notifying authority may appoint a user inspectorate to carry out conformity assessment procedures provided that—

(*a*) the inspectorate meets the requirements of Article 25 of the Directive, and

(*b*) the group of which the inspectorate is part applies a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of pressure equipment and assemblies,

(3) An appointment of a user inspectorate under paragraph (2)—

(*a*) shall be of fixed duration,

(*b*) may be subject to such conditions as the notifying authority thinks fit, for the efficient and proper functioning of a user inspectorate,

(4) Pressure equipment and assemblies the conformity of which has been assessed by a user inspectorate shall—

(*a*) not bear the CE marking,

(*b*) only be used in establishments operated by the group of which the inspectorate is part, which 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.

(5) User inspectorates appointed under paragraph (2) shall—

(*a*) act exclusively for the group of which they are part,

(*b*) apply the conformity assessment procedures at modules A2, C2, F and G of Annex III to the Directive, the text of which is set out in Schedule 3 to these Regulations.

Recognised third-party organisations

18. (1) The notifying authority may appoint an organisation to be a recognised third party organisation for the purposes of undertaking the tasks referred to in paragraphs 3.1.2 and 3.1.3 of Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations, provided that the organisation satisfies the minimum criteria set out in paragraphs 2 to 11 of Article 24 of the Directive.

(2) An appointment of a recognised third party organisation under paragraph (1)—

(*a*) shall be of fixed duration,

(*b*) may subject to such conditions as the notifying authority thinks fit, for the efficient and proper functioning of a recognised third party organisation,

EU declaration of conformity

19. (1) An EU declaration of conformity for pressure equipment or an assembly shall—

(*a*) state that the fulfilment of the essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations, has been demonstrated,

(*b*) have the model structure set out in Annex IV to the Directive, the text of which is set out in Schedule 4 to these Regulations,

(*c*) contain the elements specified in the relevant conformity assessment procedures set out in Annex III to the Directive, the text of which is set out in Schedule 3 to these Regulations,

(*d*) be continuously updated,

(*e*) 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) Where pressure equipment or an assembly is subject to more than one European Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such European Union acts, which declaration shall contain the identification of the European Union acts including their publication references.

(3) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements laid down in the Directive or these Regulations.

General principles of the CE marking

20. The CE marking when affixed to a product is subject to the general principles set down in Article 30 of Regulation (EC) No. 765/2008.

Rules and conditions for affixing the CE Marking

21. (1) Subject to paragraphs (2), (3) and (4), before the pressure equipment or assembly is placed on the market, the CE marking shall be affixed visibly, legibly and indelibly to—

(*a*) each item of pressure equipment referred to in Regulation 6(1) or its dataplate, or

(*b*) each assembly referred to in Regulation 6(2) or its dataplate.

(2) Where it is not possible to affix the CE marking to the pressure equipment or assembly or where it is not warranted on account of the nature of the equipment or assembly, the CE marking shall be affixed to the packaging and to the accompanying documents.

(3) The item of pressure equipment or assembly referred to in paragraphs 1(*a*) and (*b*) shall be complete or shall be in a state permitting final assessment as described in point 3.2 of Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations.

(4) It shall not be necessary to affix the CE marking to each individual item of pressure equipment making up an assembly and individual items of pressure equipment already bearing the CE marking when incorporated into the assembly shall continue to bear that marking.

(5) The CE marking on products shall be followed by the identification number of the notified body, where that body is involved in the production

control phase and shall be affixed by the body itself or, under its instructions, by the manufacturer or its authorised representative.

(6) The CE marking and, where applicable, the identification number referred to in paragraph (5) may be followed by any other mark indicating a special risk or use.

PART 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Notified bodies, recognised third-party organisations, user inspectorates

22. (1) The notifying authority shall notify the European Commission and the other Member States of—

(*a*) the notified bodies authorised under these Regulations to carry out conformity assessment tasks in accordance with Article 14 and 15 of the Directive and Regulation 15 and 16 of these Regulations,

(*b*) the third-party organisations the authority has recognised, for the purposes of the tasks referred to in points 3.1.2 and 3.1.3 of Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations, and

(*c*) the user inspectorates authorised under these Regulations to carry out conformity assessment tasks in accordance with Article 16 of the Directive and Regulation 17 of these Regulations.

(2) Only bodies which have been notified to the European Commission and other Member States in accordance with these Regulations and against whom no objections are raised by the European Commission or other Member States within the time periods set down under Article 29(5) of the Directive, shall be a notified body, third-party organisation or user inspectorate, as appropriate, for the purposes of the Directive and these Regulations.

Application for notification by conformity assessment bodies

23. (1) A conformity assessment body seeking to become a notified body shall meet the requirements set down in paragraphs 2 to 11 of Article 24 of the Directive.

(2) A conformity assessment body seeking to become a recognised third-party organisation shall meet the requirements set down in paragraphs 2 to 11 of Article 24 of the Directive.

(3) A conformity assessment body seeking to become a user inspectorate shall meet the requirements set down in paragraphs 2 to 11 of Article 25 of the Directive.

(4) Without prejudice to paragraphs (1) and (2) where a conformity assessment body seeking to become a notified body or a recognised third-party organisation 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, it shall be presumed to comply with the requirements of Article 24 in so far as the applicable harmonised standards cover those requirements.

(5) Without prejudice to paragraph (3) where a conformity assessment body seeking to become a user inspectorate demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references to which have been published in the Official Journal, it shall be presumed to comply with the requirements of Article 25 in so far as the applicable harmonised standards cover those requirements.

(6) A conformity assessment body seeking to become a notified body, a recognised third-party organisation or a user inspectorate shall submit to the notifying authority an application, which application shall be in accordance with Article 28 of the Directive and shall be accompanied by the appropriate fee as may be prescribed by the notifying authority.

Notification of conformity assessment bodies

24. (1) The notifying authority may only notify a conformity assessment body where that body—

(*a*) has made an application in accordance with Article 28 of the Directive, and

(*b*) meets the requirements of Article 24 of the Directive in the case of a body seeking to become a notified body or a recognised third-party organisation or of Article 25 of the Directive in the case of a body seeking to become a user inspectorate.

(2) Notifications by the notifying authority under paragraph (1) shall be made in accordance with the notification procedure set down in Article 29(2), (3) and (4) of the Directive.

(3) The notifying authority shall notify the European Commission and the other Member States of any subsequent relevant changes to the notification.

(4) The assessment and monitoring referred to in Article 21(2) of the Directive shall be carried out by the Irish National Accreditation Board.

Changes to notifications

25. (1) Where the notifying authority has ascertained or has been informed that a notified body or a recognised third-party organisation no longer meets the requirements in Article 24 of the Directive, or that it is failing to fulfil its obligations under the Directive or these Regulations, that authority shall restrict, suspend, or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

(2) Where the notifying authority has ascertained or has been informed that a user inspectorate no longer meets the requirements in Article 25 of the Directive, or that it is failing to fulfil its obligations under the Directive or these

Regulations, that authority shall restrict, suspend, or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

(3) In the event of restriction, suspension or withdrawal of notification under paragraphs (1) or (2) the notifying authority shall immediately inform the European Commission and the other Member States of the restriction, suspension or withdrawal of same.

(4) In the event of restriction, suspension or withdrawal of notification under paragraphs (1) or (2) or where the notified body, recognised third-party organisation or user inspectorate has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of the relevant body are either processed by another notified body, recognised third party organisation or user inspectorate or kept available for the responsible notifying and competent authorities at their request.

(5) The notifying authority shall inform the notified body, recognised third-party organisation or user inspectorate of any decision under paragraphs (1) and (2) and allow that body an opportunity to make representations to it.

(6) The notifying authority shall establish one panel per appeal ("appeal panel") for the purposes of considering appeals under this Regulation. An appeal panel shall consist of at least 3 but not more than 5 persons appointed by the notifying authority, one of whom shall be designated by the notifying authority to be chairperson of the panel. An appeal panel shall not consist of any person who decided or was involved in the decision to restrict, suspend or withdraw the relevant notification pertaining to a notified body, recognised third party organisation or user inspectorate. An appeal panel shall establish its own procedure.

(7) Where the notifying authority decides to restrict, suspend or withdraw notification pertaining to a notified body, recognised third party organisation or user inspectorate, that body may, within 14 days of the notification under paragraph (5), appeal to an appeal panel against the restriction, suspension or withdrawal, as the case may be. The notification pertaining to a notified body, recognised third party organisation or user inspectorate stands restricted, suspended or withdrawn, as the case may be, from the date of the notification of the decision under paragraph (5), unless the appeal panel, upon an application to it, decides otherwise, pending the outcome of the appeal. On hearing the appeal the appeal panel may confirm the decision, vary it or allow the appeal and shall notify the appellant of its decision. The decision of the appeal panel is final except that an appeal lies to the High Court on application to it on a specified point of law. Such an application does not affect the decision of the appeal panel and its operation.

(8) All expenses reasonably incurred by the notifying authority in relation to an appeal before an appeal panel or the High Court shall be borne by the appellant where the appeal panel or the court confirms or confirms with a variation the decisions of the notifying authority. The notifying authority may

recover these expenses as a simple contract debt in a court of competent jurisdiction.

Subsidiaries of and subcontracting by conformity assessment bodies

26. Where a notified body, recognised third-party organisation or user inspectorate subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall comply with Article 27 of the Directive.

Operational obligations of notified bodies, user inspectorates and recognised third party organisations

27. (1) Subject to paragraph (2) notified bodies, recognised third-party organisations and user inspectorates shall—

(*a*) carry out conformity assessments in accordance with the conformity assessment tasks provided for in Article 14, Article 15, Article 16 of the Directive or in points 3.1.2 and 3.1.3 of Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations, as appropriate,

(*b*) ensure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for economic operators,

(*c*) 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,

(*d*) in a case where they find that the essential safety requirements set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations, or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity,

(*e*) in a case where, in the course of the monitoring of conformity following the issue of a certificate, the notified body, recognised third-party organisation or user inspectorate finds that pressure equipment no longer complies, require the manufacturer to take appropriate corrective measures and suspend or withdraw the certificate if necessary,

(*f*) in a case where corrective measures under paragraph (*e*) are not taken by the manufacturer or do not have the required effect, restrict, suspend or withdraw any certificates, as appropriate,

(*g*) inform the manufacturer in question where a decision to restrict, suspend or withdraw any certificate is taken under paragraph (*f*), and

(*h*) participate in the sectoral group of notified bodies, third party organisations or user inspectorates in accordance with Article 38 of the Directive.

(2) In carrying out their functions under paragraph 1(*b*) and 1(*c*) of this Regulation, the notified body, recognised third-party organisation or user inspectorate shall nevertheless respect the degree of rigour and the level of protection required for the compliance of pressure equipment with the Directive or these Regulations.

Appeal against decisions of notified bodies, recognised third-party organisations and user inspectorates

28. (1) The notifying authority shall establish one panel per appeal ("appeal panel") for the purposes of considering appeals against restrictions, suspensions or withdrawals rendered by a notified body, recognised third-party organisations or user inspectorate under Regulation 27. An appeal panel shall consist of at least 3 but not more than 5 persons appointed by the notifying authority, one of whom shall be designated by the notifying authority to be chairperson of the panel. An appeal panel shall not consist of any person who decided or was involved in the decision to restrict, suspend or withdraw the relevant certificate or approval decision. An appeal panel shall establish its own procedure.

(2) Where a notified body, recognised third-party organisation or user inspectorates decides to restrict, suspend or withdraw a certificate held by a manufacturer, the latter may, within 14 days of the notification under Regulation 27(1)(*g*), appeal to an appeal panel against the restriction, suspension or withdrawal, as the case may be. The certificate or approval decision stands restricted, suspended or withdrawn, as the case may be, from the date of notification of the decision under Regulation 27(1)(*g*), unless the appeal panel, upon an application to it, decides otherwise, pending the outcome of the appeal. On hearing the appeal the appeal panel may confirm the decision, vary it or allow the appeal and shall notify the appellant of its decision. The decision of the appeal panel is final except that an appeal lies to the High Court on application to it on a specified point of law. Such an application does not affect the decision of the appeal panel and its operation.

Information obligation on notified bodies, recognised third-party organisations and user inspectorates

29. (1) Notified bodies, recognised third-party organisations and user inspectorates shall—

(*a*) inform the notifying authority of the matters referred to in Article 36(1)(*a*), (*b*), (*c*) and (*d*) of the Directive,

(*b*) provide other bodies notified under the Directive or these Regulations carrying out similar conformity assessment activities covering the same pressure equipment with relevant information on issues relating to negative conformity assessment results, and

(*c*) on request, provide other bodies notified under the Directive or these Regulations carrying out similar conformity assessment activities covering the same pressure equipment with relevant information on issues relating to positive conformity assessment results.

PART 5

MARKET SURVEILLANCE, SAFEGUARD PROCEDURE

Market surveillance

30. The market surveillance authority shall organise and carry out market surveillance of pressure equipment and assemblies covered by these Regulations in accordance with Articles 16 to 29 of Regulation (EC) No. 765/2008.

Procedure for dealing with pressure equipment or assemblies presenting a risk at national level

31. (1) Where the market surveillance authority has sufficient reason to believe that pressure equipment or assemblies covered by these Regulations presents a risk to the health and safety of persons or to domestic animals or property, it shall carry out an evaluation in relation to the product concerned covering all requirements laid down in the Directive or these Regulations.

(2) The relevant economic operator shall cooperate as necessary with the market surveillance authority in carrying out an evaluation under paragraph (1).

(3) Where, in the course of an evaluation referred to in paragraph (1), the market surveillance authority finds that the pressure equipment or assembly does not comply with the requirements laid down in the Directive or these Regulations, it shall—

(*a*) 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 product from the market or to recall it within a reasonable period commensurate with the nature of the risk, as the authority prescribes,

(*b*) inform the notified body who carried out the conformity assessment procedure on the pressure equipment or assembly of the non-compliance of that equipment or assembly, and

(*c*) apply the provisions of Article 21 of Regulation (EC) No. 765/2008 to the measures referred to in paragraph 3(*a*) of this Regulation.

(4) Where the market surveillance authority considers that non-compliance is not restricted to the State, it shall inform the European Commission and the other Member States of the results of the evaluation and of the actions which it has required the economic operator to take.

(5) The relevant economic operator shall ensure that all appropriate corrective action is taken in respect of all the products concerned that it has made available on the market throughout the European Economic Area.

(6) Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 3(*a*) of this Regulation, the market surveillance authority shall, without delay, take all appropriate provisional measures to prohibit or restrict the pressure equipment or assembly

from being made available on the market in the State, to withdraw the pressure equipment or assembly from that market or to recall it.

(7) The market surveillance authority shall inform the European Commission and the other Member States, without delay, of any measures taken under paragraph (6) and shall—

(*a*) include all available details, in particular the data necessary for the identification of the non-compliant pressure equipment or assembly, the origin of the pressure equipment or assembly, the nature of the non-compliance alleged and the risk involved, the nature and duration of the measures taken in the State and the arguments put forward by the relevant economic operator, and

(*b*) in particular, indicate whether the non-compliance is due to either—

(i) the failure of the product to meet requirements relating to the health or safety of persons, or to the protection of domestic animals or property, or

(ii) shortcomings in the harmonised standards referred to in Regulation 13 conferring a presumption of conformity.

(8) Where another Member State has initiated the procedure under Article 40 of the Directive, the market surveillance authority shall, without delay, inform the European Commission and the other Member States—

(*a*) of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned, or

(*b*) of its objections, in the event of disagreement with the adopted measure adopted of the other Member State.

(9) Where, within three months of receipt of the information referred to in paragraph (7), no objection has been raised by either a Member State or the European Commission in respect of a provisional measure taken by the market surveillance authority, that measure shall be deemed to be justified.

(10) The market surveillance authority shall ensure that appropriate restrictive measures, such as the withdrawal of the product from the market, are taken in respect of the product concerned without delay.

Safeguard procedure

32. (1) Where a national measure taken by a Member State under Article 40 of the Directive is considered justified by the European Commission in accordance with the procedure in Article 41(1) of the Directive, the market surveillance authority shall take the necessary measures to ensure that the non-compliant product is withdrawn from the market in the State and shall inform the European Commission accordingly.

(2) Where a national measure taken by a Member State under Article 40 of the Directive is considered unjustified by the European Commission in accordance with the procedure in Article 41(1) of the Directive, the market surveillance authority shall withdraw that measure.

Compliant pressure equipment or assemblies which present a risk

33. (1) Where, having carried out an evaluation under Regulation 31, the market surveillance authority finds that, although a product is in compliance with the Directive or these Regulations, it presents a risk to the health and safety of persons or to domestic animals or property, it shall—

(*a*) require the economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe, and

(*b*) immediately inform the European Commission and the other Member States of all available details and in particular of—

(i) the data necessary for the identification of the product concerned,

(ii) the origin and supply chain of the product,

(iii) the nature of the risk involved, and

(iv) the nature and duration of the national measures taken.

(2) An economic operator shall ensure that the corrective action required under paragraph (1) is taken in respect of all products concerned that the operator has placed or made available on the market throughout the European Economic Area.

Formal non-compliance

34. (1) Without prejudice to Regulation 31, the market surveillance authority shall require the relevant economic operator to put an end to the non-compliance concerned where it finds that—

(*a*) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No. 765/2008, Article 19 of the Directive, or Regulation 21 of these Regulations,

(*b*) the CE marking has not been affixed,

(*c*) the identification number of the notified body involved in the production control phase, has been affixed in violation of Article 19 of the Directive or Regulation 21(5) or has not been affixed,

(*d*) the marking and labelling referred to in point 3.3. of Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations, have not been affixed or have been affixed in violation of Regulation 21 or point 3.3 of Annex I to the Directive,

(*e*) the EU declaration of conformity has not been drawn up,

(*f*) the EU declaration of conformity has not been drawn up correctly,

(*g*) the technical documentation is either not available or not complete,

(*h*) the information referred to in Regulation 7(*i*) or Regulation 9(2)(*d*) is absent, false or incomplete;

(*i*) any other administrative requirement provided for in Article 6 or 8 of the Directive or Regulation 7 or Regulation 9 is not fulfilled.

(2) Where the non-compliance referred to in paragraph 1 persists, the market surveillance authority shall take all appropriate measures to restrict or prohibit the making available on the market of the product or ensure that it is recalled or withdrawn from the market.

PART 6

POWERS OF THE MARKET SURVEILLANCE AUTHORITY

General

35. (1) The market surveillance authority shall perform its market surveillance duties in accordance with the relevant provisions of Article 39 of the Directive.

(2) A person who for the time being stands appointed as an inspector under section 62 of the Act of 2005 shall be an inspector for the purposes of the Directive and these Regulations.

(3) An inspector shall, when exercising any power conferred on him or her by these Regulations, if requested to do so by any person affected, produce the certificate of authorisation or a copy of it furnished to him or her under section 62(2) of the Act of 2005 together with a form of personal identification.

Powers of inspectors

36. (1) An inspector shall, for the purposes of these Regulations, have power to do any one or more of the following:

(*a*) subject to paragraph (4), at any time enter—

(i) the premises of an economic operator, or

(ii) any other place or premises where entry on same is necessary to ensure that the objectives of the Directive are achieved;

(*b*) inquire into, search, examine and inspect—

(i) any place referred to in paragraph 1(*a*),

(ii) any activity, installation, process, procedure, matter or thing at or in that place, and

(iii) any pressure equipment or assembly or any record relating to such pressure equipment or assembly, to ascertain whether the Directive or these Regulations have been or are being complied with and, for that purpose, take with him or her and use any equipment or materials he or she consider necessary;

(*c*) require that that place and anything at or in it be left undisturbed for so long as is reasonably necessary for the purposes of any search, examination, investigation, inspection or inquiry under the Directive or these Regulations;

(*d*) require the person in charge to produce to the inspector—

(i) any product or partly completed product which is in the possession or under the control of such person, and

(ii) any records, and in the case of such information in a non-legible form, to reproduce it in a legible form, and to give to the inspector such information as the inspector may reasonably require in relation to any entries in those records;

(*e*) inspect and take copies of or extracts from any such records or any electronic information system at that place, including in the case of information in a non-legible form, copies of or extracts from such information in a permanent legible form or require that such copies be provided;

(*f*) require a person at or in that place by whom or on whose behalf a computer is or has been used to produce or store records or any person having control of, or otherwise concerned with the operation of the computer, to afford the inspector access thereto and all reasonable assistance as the inspector may require;

(*g*) remove from that place and retain the records (including documents stored in a non-legible form) and copies taken and detain the records for such period as the inspector reasonably considers to be necessary for further examination or until the conclusion of any legal proceedings;

(*h*) require that records at or in that place be maintained for such period as may be reasonable;

(*i*) require the person in charge to give the inspector such information as the inspector may reasonably require for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;

(*j*) require the person in charge to give the inspector such assistance and facilities within the person's power or control as are reasonably necessary to enable the inspector to exercise any of his or her powers under these Regulations;

(*k*) require by notice, at a time and place specified in the notice, any person (including the person in charge) to give the inspector any information that the inspector may reasonably require in relation to the place, any product, equipment, item, activity, installation or procedure at or in the place, and to produce to the inspector any records that are under that person's power or control;

(*l*) examine any person whom the inspector reasonably believes to be able to give to the inspector information relevant to any search, examination, investigation, inspection or inquiry under these Regulations and require the person to answer such questions as the inspector may ask relative to the search, examination, investigation, inspection or inquiry and to sign a declaration of the truth of the answers;

(*m*) require that any procedure be followed for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;

(*n*) take any measurements or photographs or make any tape, electrical or other recordings that the inspector considers necessary for the purposes of any search, examination, investigation, inspection or inquiry under the Directive or these Regulations;

(*o*) take samples of air, soil, water or waste at or near that place;

(*p*) where appropriate, install, use and maintain at that place monitoring instruments, systems and seals for the purposes of the Directive or these Regulations;

(*q*) at that place, or at any other location, carry out, or have carried out, such testing, examination or analysis of any item or product found at that place, as he or she reasonably considers to be necessary, and for that purpose—

(i) require the person in charge to supply to the inspector without charge any product, equipment or item, or samples thereof, or

(ii) remove, or have removed, to another location, any product, equipment or item, or samples thereof;

(*r*) cause any pressure equipment or assembly found at that place in respect of which there has been or there appears to the inspector to have been a contravention of the Directive or these Regulations, to be subjected to any testing, examination or analysis in accordance with subparagraph (*q*) (but not so as to damage or destroy it unless necessary for the purposes of the Directive or these Regulations) and where an inspector proposes to exercise the power conferred by this subparagraph in the case of any such product found at any place, he or she shall, if so requested by the person in charge, cause anything that is to be done by virtue of that power to be done in the presence of that person, save that the person in charge is responsible for his or

her own costs in attending at the exercise of the inspector's powers and cannot unreasonably delay the inspector in the exercise of those powers;

(*s*) remove and retain for such period as is necessary any product, equipment or item found at that place for all or any of the following purposes:

(i) to examine or arrange for the examination, testing or analysis of the product, equipment or item;

(ii) to ensure that it is not tampered with before the examination of it under subparagraph (i) is completed;

(iii) to ensure that it is available for use as evidence in any proceedings;

(*t*) where necessary—

(i) require the disposal of any product presenting a serious risk in respect of which there has been or there appears to the inspector to have been a contravention of the Directive or these Regulations at the expense of the person in charge, or remove that product and arrange for it to be disposed of at the expense of the person in charge, and

(ii) require that such disposal shall be—

(I) such as will prevent the product from being used or placed or made available on the market, and

(II) in compliance with requirements under the Waste Management Acts 1996 to 2003;

(*u*) require the recall or removal from the market of a product by the person who has placed or made available that product on the market, where it appears to the inspector that, in relation to that product, the Directive or these Regulations have been contravened.

(2) Where a product is found at a place, and an inquiry is made by an inspector in the course of a search, examination, investigation or inspection as to the identity of the person who supplied that product, the person in charge shall give the inspector the name and address of the supplier from whom the product was purchased or otherwise obtained.

(3) Before exercising any of the powers conferred by subparagraphs (*q*) to (*t*) of paragraph (1), an inspector shall, in so far as it is practicable, consult such persons as appear to him or her to be appropriate for the purpose of ascertaining what dangers, if any, there may be in doing what he or she proposes to do under those subparagraphs.

(4) An inspector shall not enter a dwelling other than—

(*a*) with the consent of the occupier, or

(*b*) in accordance with a warrant of the District Court issued under paragraph (7) authorising such entry.

(5) The market surveillance authority may authorise such and so many other persons as it considers appropriate to accompany an inspector in the performance of his or her functions.

(6) Where an inspector in the exercise of his or her powers under this Regulation is prevented from entering any of the places or premises specified in Regulation 36(1)(*a*), an application may be made to the District Court for a warrant under paragraph (7) authorising such entry.

(7) Without prejudice to the powers conferred on an inspector by or under any other provision of this Regulation, if a judge of the District Court is satisfied by information on oath of an inspector that there are reasonable grounds for believing that—

(*a*) there is any product, equipment or item at any place or premises any records (including documents stored in a non-legible form) or information, relating to a place, premises or to any pressure equipment or assembly, that the authorised officer requires to inspect for the purposes of these Regulations, held at any place or premises, or

(*b*) there is, or such an inspection is likely to disclose, evidence of a contravention of the Directive or these Regulations,

the judge may issue a warrant authorising an inspector, accompanied by such other inspectors or such other competent persons as may be appropriate or members of the Garda Síochána as may be necessary, at any time or times, within one month from the date of issue of the warrant, on production of the warrant if requested, to enter that place or premises, if necessary by the use of reasonable force, and perform the functions conferred on an inspector by or under these Regulations.

(8) Where an inspector has reasonable grounds for apprehending any serious obstruction in the performance of his or her functions or otherwise considers it necessary, he or she may be accompanied by a member or members of the Garda Síochána and by any other person or persons authorised by the market surveillance authority, when performing any functions conferred on him or her by or under these Regulations.

(9) Where an inspector, upon reasonable grounds, believes that a person has committed an offence under these Regulations he or she may require that person to provide him or her with the person's name and the address at which the person ordinarily resides.

(10) A statement or admission made by a person pursuant to a requirement under paragraph (1)(*i*), (*k*) or (*l*) shall not be admissible in proceedings brought against that person for an offence (other than an offence under Regulation 46(4)) relating to a breach of, or failure to comply with, an obligation in the said paragraph (1) (*i*), (*k*) or (*l*).

Measures entailing refusal or restriction

37. An inspector who finds that—

(*a*) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No. 765/2008, Article 19 of the Directive, or Regulation 21 of these Regulations,

(*b*) the CE marking has not been affixed,

(*c*) the identification number of the notified body involved in the production control phase, has been affixed in violation of Article 19 of the Directive or Regulation 21(5) or has not been affixed,

(*d*) the marking and labelling referred to in point 3.3 of Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations, have not been affixed or have been affixed in violation of Regulation 21 or point 3.3 of Annex I to the Directive,

(*e*) the EU declaration of conformity has not been drawn up,

(*f*) the EU declaration of conformity has not been drawn up correctly,

(*g*) the technical documentation is either not available or not complete,

(*h*) the information referred to in Regulation 7(i) or Regulation 9(2)(*d*) is absent, false or incomplete,

(*i*) any other administrative requirement provided for in Article 6 or 8 of the Directive or Regulation 7 or Regulation 9 is not fulfilled,

may issue a direction in writing to the relevant economic operator to put an end to the non-compliance observed within a specified timeframe.

Contravention notice

38. (1) An inspector who is of the opinion that a person—

(*a*) is contravening or has contravened any of the provisions of the Directive or these Regulations, or

(*b*) has failed to comply with a direction under Regulation 37,

may serve a notice on the person who has or may reasonably be presumed to have control of the activity concerned.

(2) A contravention notice shall—

(*a*) state that the inspector is of the opinion referred to in paragraph (1),

(*b*) specify the grounds for the inspector being of the opinion referred to in paragraph (1) and specify the Regulation or Regulations concerned,

(*c*) identify the relevant provision in respect of which that opinion is held,

(*d*) direct the person, where required, to—

(i) remedy, by a date specified in the notice, the contravention or the matters occasioning that notice, or

(ii) cease placing or making available the product on the market or putting it into use,

(iii) remove the product from the market,

(iv) recall the product,

(v) dispose of the product,

(vi) destroy the product where it presents a serious risk,

by a date specified in the notice that shall not be earlier than the end of the period within which an appeal may be made under Regulation 39(1),

(*e*) include information regarding the making of an appeal under Regulation 39(1) and (2),

(*f*) include any other requirement that the inspector considers appropriate, and

(*g*) state that if the person to whom the notice is addressed fails to take such measures as are specified in the notice within the time period specified in that notice, that person commits an offence, and

(*h*) be signed and dated by the inspector.

(3) A contravention notice may include directions—

(*a*) as to the measures to be taken to remedy any contravention or matter to which the notice relates, or to otherwise comply with the notice, and

(*b*) to bring the notice to the attention of any person who may be affected by it, or the public generally.

(4) A person on whom a contravention notice has been served who is of the opinion that the contravention notice has been complied with shall confirm in

writing to the inspector that the matters referred to in the notice have been so remedied.

(5) Where a person on whom a contravention notice has been served so confirms in writing to the inspector in accordance with paragraph (4) that the matters referred to in the contravention notice have been remedied, the inspector shall, on being satisfied that the matters have been so remedied, within one month of receipt of such confirmation, give notice to the person concerned of compliance with the contravention notice.

(6) An inspector may—

(*a*) withdraw or amend a contravention notice at any time, or

(*b*) where no appeal is made or pending under Regulation 39(1), extend the period specified under paragraph 2(*d*) of this Regulation.

(7) Where there is no appeal under Regulation 39(1), the contravention notice shall take effect on the later of—

(*a*) the end of the period for making an appeal, or

(*b*) the day specified in the notice.

(8) A person shall comply with a contravention notice under this Regulation.

Appeal against contravention notice

39. (1) A person aggrieved by a contravention notice may, within 14 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the district court district in which the notice was served and, in determining the appeal the judge may, if he or she is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.

(2) A person who appeals under paragraph (1) shall at the same time notify the market surveillance authority of the appeal and the grounds for the appeal and the authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal.

(3) Where an appeal under paragraph (1) is taken, and the contravention notice is not cancelled, the notice shall take effect on the later of—

(*a*) the day next following the day on which the notice is confirmed on appeal or the appeal is withdrawn, or

(*b*) the day specified in the notice.

(4) Subject to paragraph (5), in the case of a product which the inspector does not consider to present a serious risk requiring rapid intervention under Article 20 of EU Regulation 765/2008, the intended recipient of a measure referred to in Regulation 38(1) shall have the opportunity to make representations within

10 working days of first being advised of the inspector's intention, to the market surveillance authority in advance of the measure being taken.

(5) Where, due to the urgency of the measure referred to in Regulation 38(1), as justified in particular by public health, security or safety requirements, it is not possible to give the person concerned the opportunity to make representations in advance of the measure being taken, the market surveillance authority shall give such opportunity, as soon as may be, thereafter.

Prohibition notice

40. (1) A prohibition notice may be served by an inspector—

(*a*) on the person who is or who may reasonably be presumed to be in control of the activity concerned, where that inspector is of the opinion that at any place there is occurring or is likely to occur any activity relating to a product that gives rise to or is likely to give rise to a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, or

(*b*) on any person in relation to a product in respect of which a direction under Regulation 37 or a contravention notice has been issued but not complied with.

(2) A prohibition notice shall—

(*a*) state that the inspector is of the opinion referred to in paragraph (1),

(*b*) state the reason for that opinion,

(*c*) specify the activity in respect of which that opinion is held,

(*d*) where in the opinion of the inspector the activity involves a contravention, or likely contravention of any provision of the Directive or these Regulations, specify the provision,

(*e*) prohibit the carrying on of the activity concerned until the matters that give rise or are likely to give rise to the risk are remedied,

(*f*) inform the person concerned that he or she may appeal the prohibition notice to the District Court in accordance with Regulation 41(1),

(*g*) state that if the person to whom the prohibition notice is addressed fails to comply with the notice within the time period specified in the notice, the person commits an offence, and

(*h*) be signed and dated by the inspector.

(3) A prohibition notice may include directions—

(*a*) as to the measures to be taken to remedy any contravention or matter to which the notice relates, or to otherwise comply with the notice, and

(*b*) to bring the notice to the attention of any person who may be affected by it, or to the attention of the public generally.

(4) A prohibition notice shall take effect—

(*a*) when the notice is received by the person on whom it is served, or

(*b*) where an appeal is brought against the prohibition notice, on the day immediately following—

(i) the day on which the notice is confirmed on appeal or the appeal is withdrawn, or

(ii) the day specified in the notice,

whichever occurs later.

(5) A person on whom a prohibition notice has been served who is of the opinion that the matters referred to in the prohibition notice have been remedied by the date specified in the notice shall confirm in writing to the inspector that those matters have been so remedied.

(6) Where a person on whom a prohibition notice has been served confirms in writing to the inspector in accordance with paragraph (5) that the matters referred to in the prohibition notice have been remedied, the inspector shall, on being satisfied that the matters have been so remedied, within one month of receipt of such confirmation, give notice to the person concerned of such compliance with the prohibition notice.

(7) An inspector may at any time withdraw a prohibition notice if—

(*a*) the inspector is satisfied that the activity to which the notice relates no longer gives rise to a serious risk to safety or health, or

(*b*) the inspector is satisfied that the notice was issued in error or is incorrect in some material respect.

(8) A person shall comply with a prohibition notice under this Regulation.

Appeal against prohibition notice

41. (1) A person on whom a prohibition notice is served may, within 7 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the district court district in which the notice was served and in determining the appeal the judge may, if he or she is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.

(2) Where, on the hearing of an appeal under this Regulation, a prohibition notice is confirmed, notwithstanding Regulation 40(4), the judge by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition notice for such period as in the circumstances of the case the judge considers appropriate.

(3) A person who—

(*a*) brings an appeal under paragraph (1), or

(*b*) applies for the suspension of the operation of a prohibition notice under this Regulation,

shall at the same time notify the market surveillance authority of the appeal or the application, and the grounds for the appeal or application.

(4) In the case of an appeal or any application to suspend the operation of the prohibition notice under this Regulation, the market surveillance authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or application.

(5) The bringing of an appeal against a prohibition notice shall not have the effect of suspending the operation of the notice but the appellant may apply to the court to have the operation of the notice suspended until the appeal is disposed of and, on such application, the court may, if it thinks proper to do so, direct that the operation of the notice be suspended until the appeal is disposed of.

Order of the High Court

42. (1) Where a person contravenes a prohibition notice an inspector may apply ex parte to the High Court for an order prohibiting the continued contravention of the notice.

(2) The High Court may, upon an application under this Regulation, order the person on whom the prohibition notice concerned was served to cease doing such acts as the High Court directs.

Information notice

43. (1) An inspector or the market surveillance authority may, by notice served on a person, require the person to give, within such period and in such form as may be specified in the notice, any information that the inspector or the market surveillance authority may reasonably require for the proper performance by it of his or her or its functions under the Directive or these Regulations.

(2) Upon the written application of the person on whom the notice is served, the period specified in the information notice may be extended by and at the discretion of—

(i) the market surveillance authority, or

(ii) an inspector.

(3) A person on whom an information notice is served may, within 7 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the district court district in which the notice was served and in determining the appeal the judge may, if he or she is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.

(4) A person who appeals under paragraph (3) shall at the same time notify the market surveillance authority of the appeal and the grounds for the appeal and the authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal.

(5) Where, on the hearing of an appeal under paragraph (3), an information notice is confirmed or varied, the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the notice for such period as in the circumstances of the case the judge considers appropriate.

(6) Subject to paragraph (7), a person on whom an information notice is served shall comply with the notice before the later of—

(*a*) the end of the period specified in the notice, or

(*b*) where the period referred to in subparagraph (*a*) is extended under paragraph (2), the end of that extended period.

(7) Where an appeal is brought under this Regulation, and the information notice to which the appeal relates is confirmed or varied or the appeal is withdrawn, the person on whom the notice is served shall comply with the notice before—

(*a*) the day immediately following the day on which the notice is confirmed or varied or the appeal is withdrawn,

(*b*) the end of the period specified in the notice, or

(*c*) where the operation of the notice has been suspended under paragraph (5), the end of the period of suspension,

whichever occurs latest.

Service of notifications

44. (1) Subject to paragraphs (2) and (3), a notice or other document required or authorised to be served on, sent or given to a person shall be addressed to the person concerned by name and may be given to the person in one of the following ways—

(*a*) by delivering it to the person,

(*b*) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address,

(*c*) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address,

(*d*) if the person concerned has agreed to service of notices by means of an electronic communication (within the meaning assigned by section 2 of the Electronic Commerce Act 2000), service by such means, provided that there is a facility for confirming receipt of electronic communication and that such receipt has been confirmed, or

(*e*) if the address at which the person ordinarily resides cannot be ascertained by reasonable enquiry and the compliance notice relates to a premises, by delivering it to the premises or by affixing it in a conspicuous position on or near the premises,

(*f*) by any other means that may be prescribed.

(2) Where a notice or other document required or authorised to be served on, sent or given to a person is to be given to a person who is the owner or occupier of land or property and the name of the person cannot be ascertained by reasonable inquiry, it may be addressed to the person by using the words "the owner" or, as the case may require, "the occupier".

(3) For the purposes of this Regulation, a company within the meaning of the Companies Acts shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

Sharing information on the application of the Directive

45. (1) The market surveillance authority may provide information to any European Union information network, the European Commission or a competent authority of another Member State for the purpose of sharing information related to the application of the Directive.

(2) The market surveillance authority may, in the interest of the protection of safety, take such measures as it considers appropriate to bring to the attention of the public, any matter of concern arising from the requirements of these Regulations.

PART 7

OFFENCES AND PENALTIES

Offences

46. (1) A person who contravenes a provision or requirement of Regulation 5, 7, 8(3), 9, 10, 12, 31(2), 31(5) or 33(2) commits an offence.

(2) A person who contravenes a requirement of Regulation 36, 37, 38, 40 or 43 or a notice issued or measure taken thereunder commits an offence.

(3) A person who, in relation to the CE marking or any document required for the purposes of these Regulations—

(*a*) forges or counterfeits any such document,

(*b*) gives or signs a document or makes a marking knowing it to be false in any material particular,

(*c*) knowingly uses a marking or document so forged or counterfeited, or which is false as aforesaid,

(*d*) knowingly uses as applying to any person or product a marking or document which does not so apply,

(*e*) knowingly connives at any such forging, counterfeiting, giving, signing, or using,

(*f*) knowingly makes a false entry in any such document which is so required to be kept, served or sent,

(*g*) knowingly uses any such false entry, or

(*h*) knowingly has, without lawful authority, a forged marking or document or an altered marking or document in his or her possession,

commits an offence.

(4) Any person who obstructs or interferes with an inspector or a member of the Garda Síochána in the course of exercising a power conferred on him or her by these Regulations or a warrant under Regulation 36(7) or impedes the exercise by the inspector or member, as the case may be, of such power, or fails or refuses to comply with a request or requirement of, or to answer a question asked by, an inspector or such a member pursuant to a power conferred by these Regulations, or in purported compliance with such request or requirement, or who in answer to such question gives information to the inspector or member that he or she knows to be false or misleading in any material respect, commits an offence.

(5) A person who falsely represents himself or herself to be an inspector commits an offence.

(6) A person who, at any time during the period of 3 months immediately following the affixing of a notice in accordance with Regulation 44(1)(*e*) removes, alters, damages or defaces the notice without lawful authority commits an offence.

(7) A person who, prevents or attempts to prevent any person from answering any question to which an inspector may require an answer under Regulation 36, commits an offence.

(8) A person who, fails to comply with a bona fide request, instruction or directions from an inspector in the exercise of his or her functions under these Regulations, commits an offence.

(9) Where an offence under any of these Regulations is committed by reason of a failure to do something at or within a time fixed by or under any of those provisions, the offence shall be deemed to continue until that thing is done.

(10) A person who states to the market surveillance authority that another person has committed an offence under this Regulation or has failed to comply with a provision of these Regulations, knowing the statement to be false, commits an offence.

(11) A person who, in purported compliance with a requirement in an information notice, furnishes information to the market surveillance authority that he or she knows to be false or misleading in a material respect commits an offence.

Penalties

47. (1) A person guilty of an offence under Regulation 46 shall be liable—

(*a*) on summary conviction, to a class A fine or imprisonment for a term not exceeding 6 months or both, or

(*b*) on conviction on indictment, to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both.

(2) Where a person is convicted of an offence under these Regulations in proceedings brought by the market surveillance authority, or instituted following an investigation by the authority, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the authority the costs and expenses, measured by the court, incurred by the authority in relation to the investigation, detection and prosecution of the offence, including the costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisers engaged by the authority.

Offences by bodies corporate

48. Where an offence under these Regulations has been committed by a body corporate and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a person being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person as well as the body corporate commits an offence and shall be liable to be proceeded against and punished as if he or she had committed the first-mentioned offence.

Prosecution of offences

49. (1) Subject to paragraph (2), summary proceedings in relation to an offence under these Regulations may be brought and prosecuted by the market surveillance authority.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under Regulation 46 may be instituted at any time within 12 months from the date on which the offence was committed or alleged to have been committed.

PART 8

MISCELLANEOUS

Appeal to Circuit Court from certain orders of District Court

50. For the avoidance of doubt, an order of the District Court confirming, varying or cancelling a notice under Regulations 38, 40, or 43 is a decision of a judge of the District Court for the purposes of section 84 of the Courts of Justice Acts 1924.

Notice or direction to be in writing

51. Any notice or direction under these Regulations shall be in writing.

Immunity

52. None of the following persons, that is to say, the market surveillance authority, an inspector, or a member or a member of staff of the market surveillance authority shall be liable in damages in respect of any act done or omitted to be done by it or him or her in the performance, or purported performance, of that person's functions under these Regulations, unless the act or omission concerned was done in bad faith.

Indemnification

53. The market surveillance authority shall, subject to the provisions of any enactment or rule of law, indemnify an inspector appointed by it, or a member or a member of staff of the market surveillance authority, in respect of any act done or omitted to be done by him or her in the performance, or purported performance, of his or her functions under these Regulations as such inspector, member or member of staff, unless the act or omission concerned was done in bad faith.

Restrictions on the disclosure of information

54. A person in receipt of information as a result of the application of these Regulations shall treat same as confidential. In particular, business, professional and trade secrets shall be treated as confidential unless the divulging of such information is—

(*a*) for the purpose of the discharge of functions under these Regulations,

(*b*) made with the consent of the person to whom the information applies, or

(*c*) for the purposes of—

(i) any legal proceedings (including by means of a report to a coroner holding an inquest under the Coroners Acts 1962 and 2005 on the body of a person whose death may have been caused through personal injury), or

(ii) any investigation or special report under section 70 of the Act of 2005,

(*d*) necessary in order to protect the health and safety of persons,

(*e*) required by the provisions of these Regulations or the Directive, or

(*f*) ordered by a court of law.

Transitional

55. (1) The putting into service or the making available on the market 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 continues to be lawful.

(2) Certificates and decisions issued by conformity assessment bodies under Directive 97/23/EC shall be valid under these Regulations.

Revocation

56. The following are revoked—

(*a*) the European Communities (Pressure Equipment) Regulations 1999 (S.I. No. 400 of 1999), and

(*b*) the European Communities (Pressure Equipment) (Amendment) Regulations 2015 (S.I. No. 81 of 2015).

Regulations 2, 6, 7, 9, 10, 13, 18, 19, 21, 22, 27, 34 and 37

SCHEDULE 1

TEXT OF ANNEX I TO THE DIRECTIVE

ESSENTIAL SAFETY REQUIREMENTS

PRELIMINARY OBSERVATIONS

1. The obligations arising from the essential safety requirements listed in this Schedule for pressure equipment also apply to assemblies where the corresponding hazard exists.

2. The essential safety requirements laid down in the 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.

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.

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.

1. GENERAL

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.

1.2. In choosing the most appropriate solutions, the manufacturer shall apply the principles set out below in the following order:

— eliminate or reduce hazards as far as is reasonably practicable;

— apply appropriate protection measures against hazards which cannot be eliminated;

— 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.

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.

2. DESIGN

2.1. **General**

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.

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.

2.2. **Design for adequate strength**

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:

— internal/external pressure,

— ambient and operational temperatures,

— static pressure and mass of contents in operating and test conditions,

— traffic, wind, earthquake loading,

— reaction forces and moments which result from the supports, attachments, piping, etc.,

— corrosion and erosion, fatigue, etc.,

— decomposition of unstable fluids.

Various loadings which can occur at the same time shall be considered, taking into account the probability of their simultaneous occurrence.

2.2.2. Design for adequate strength shall be based on either of the following:

— 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,

— 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.

2.2.3. *Calculation method*

(a) Pressure containment and other loading aspects

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.

These calculation methods shall provide sufficient safety margins consistent, where applicable, with the requirements of point 7.

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:

— design by formula,

— design by analysis,

— design by fracture mechanics.

(b) Resistance

Appropriate design calculations shall be used to establish the resistance of the pressure equipment concerned.

In particular:

— 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,

— the calculation temperatures shall allow for appropriate safety margins,

— 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,

— the maximum stresses and peak stress concentrations shall be kept within safe limits,

— 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:

— yield strength, 0,2 % or 1,0 % proof strength as appropriate at calculation temperature,

— tensile strength,

— time-dependent strength, i.e. creep strength,

— fatigue data,

— Young's modulus (modulus of elasticity),

— appropriate amount of plastic strain,

— bending rupture energy,

— fracture toughness.

— 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,

— 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:

— for creep: design hours of operation at specified temperatures,

— for fatigue: design number of cycles at specified stress levels,

— for corrosion: design corrosion allowance.

(c) Stability aspects

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.

2.2.4. *Experimental design method*

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.

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.

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.

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.

The test programme shall include:

(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.

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;

(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;

(c) where necessary, additional tests concerning other factors referred to in point 2.2.1 such as corrosion, external damage.

2.3. **Provisions to ensure safe handling and operation**

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:

— closures and openings,

— dangerous discharge of pressure relief blow-off,

— devices to prevent physical access whilst pressure or a vacuum exists,

— surface temperature taking into consideration the intended use,

— decomposition of unstable fluids.

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.

2.4. **Means of examination**

(a) Pressure equipment shall be designed and constructed so that all necessary examinations to ensure safety can be carried out;

(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;

(c) Other means of ensuring the safe condition of the pressure equipment may be applied in any of the following situations:

— where it is too small for physical internal access,

— where opening the pressure equipment would adversely affect the inside,

— 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.

2.5. **Means of draining and venting**

Adequate means shall be provided for the draining and venting of pressure equipment where necessary:

— 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,

— to permit cleaning, inspection and maintenance in a safe manner.

2.6. **Corrosion or other chemical attack**

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.

2.7. **Wear**

Where severe conditions of erosion or abrasion may arise, adequate measures shall be taken to:

— minimise that effect by appropriate design, e.g. additional material thickness, or by the use of liners or cladding materials,

— permit replacement of parts which are most affected,

— draw attention, in the instructions referred to in point 3.4, to measures necessary for continued safe use.

2.8. **Assemblies**

Assemblies shall be so designed that:

— the components to be assembled together are suitable and reliable for their duty,

— all the components are properly integrated and assembled in an appropriate manner.

2.9. **Provisions for filling and discharge**

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:

(a) on filling:

— overfilling or overpressurisation having regard in particular to the filling ratio and to vapour pressure at the reference temperature,

— instability of the pressure equipment;

(b) on discharge: the uncontrolled release of the pressurised fluid;

(c) on filling or discharge: unsafe connection and disconnection.

2.10. **Protection against exceeding the allowable limits of pressure equipment**

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.

The suitable device or combination of such devices shall be determined on the basis of the particular characteristics of the equipment or assembly.

Suitable protective devices and combinations thereof comprise:

(a) safety accessories as defined in point 4 of Article 2 of the Directive,

(b) where appropriate, adequate monitoring devices such as indicators and/or alarms which enable adequateaction to be taken either automatically or manually to keep the pressure equipment within the allowable limits.

2.11. **Safety accessories**

2.11.1. Safety accessories shall:

— 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,

— be independent of other functions, unless their safety function cannot be affected by such other functions,

— 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.

2.11.2. *Pressure limiting devices*

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 point 7.3 is allowable, where appropriate.

2.11.3. *Temperature monitoring devices*

These devices shall have an adequate response time on safety grounds, consistent with the measurement function.

2.12. **External fire**

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.

3. MANUFACTURING

3.1. **Manufacturing procedures**

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.

3.1.1. *Preparation of the component parts*

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.

3.1.2. *Permanent joining*

Permanent joints and adjacent zones shall be free of any surface or internal defects detrimental to the safety of the equipment.

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.

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.

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:

— a notified body,

— a third-party organisation recognised by a Member State as provided for in Article 20 of the Directive.

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.

3.1.3. *Non-destructive tests*

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 of the Directive.

3.1.4. *Heat treatment*

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.

3.1.5. *Traceability*

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.

3.2. **Final assessment**

Pressure equipment shall be subjected to final assessment as described below.

3.2.1. *Final inspection*

Pressure equipment shall undergo a final inspection to assess visually and by examination of the accompanying documents compliance with the requirements of the 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).

3.2.2. *Proof test*

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.

For category I series-produced pressure equipment, this test may be performed on a statistical basis.

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.

3.2.3. *Inspection of safety devices*

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.

3.3. **Marking and labelling**

In addition to the CE marking referred to in Articles 18 and 19 of the Directive and the information to be provided in accordance with Article

6(6) and Article 8(3) of the Directive, the following information shall be provided:

(a) for all pressure equipment:

— the year of manufacture,

— identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number,

— essential maximum/minimum allowable limits.

(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:

— the volume V of the pressure equipment in L,

— the nominal size for piping DN,

— the test pressure PT applied in bar and date,

— safety device set pressure in bar,

— output of the pressure equipment in kW,

— supply voltage in V (volts),

— intended use,

— filling ratio kg/L,

— maximum filling mass in kg,

— tare mass in kg,

— the fluid group.

(c) where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.

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:

— where applicable, appropriate documentation may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly,

— where the pressure equipment is too small, e.g. accessories, this information may be given on a label attached to that pressure equipment,

— 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.

3.4. **Operating instructions**

(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:

— mounting including assembling of different pieces of pressure equipment,

— putting into service,

— use,

— maintenance including checks by the user.

(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.

(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.

4. MATERIALS

Materials used for the manufacture of pressure equipment shall be suitable for such application during the scheduled lifetime unless replacement is foreseen.

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.

4.1. Materials for pressurised parts shall:

(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;

(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;

(c) not be significantly affected by ageing;

(d) be suitable for the intended processing procedures;

(e) be selected in order to avoid significant undesirable effects when the various materials are put together.

4.2. The pressure equipment manufacturer shall:

(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;

(b) provide in his technical documentation elements relating to compliance with the materials specifications of the Directive in one of the following forms:

— by using materials which comply with harmonised standards,

— by using materials covered by a European approval of pressure equipment materials in accordance with Article 15 of the Directive,

— by a particular material appraisal;

(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.

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.

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.

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.

SPECIFIC PRESSURE EQUIPMENT REQUIREMENTS

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.

5. FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH A RISK OF OVERHEATING AS REFERRED TO IN ARTICLE 4(1) OF THE DIRECTIVE

This pressure equipment includes:

— steam and hot-water generators as referred to in Article 4(1)(*b*) of the Directive, 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,

— process-heating equipment for other than steam and hot water generation falling under Article 4(1)(*a*) of the Directive, such as heaters for chemical and other similar processes and pressurised food-processing equipment.

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:

(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;

(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;

(c) adequate provisions are made to eliminate risks of damage from deposits;

(d) means of safe removal of residual heat after shutdown are provided;

(e) steps are taken to avoid a dangerous accumulation of ignitable mixtures of combustible substances and air, or flame blowback.

6. PIPING AS REFERRED TO IN ARTICLE 4(1)(*c*) OF THE DIRECTIVE

Design and construction shall ensure:

(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;

(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;

(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;

(d) that due consideration is given to the risk of fatigue due to vibrations in pipes;

(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;

(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;

(g) that the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection or repair.

7. SPECIFIC QUANTITATIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT

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.

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.

7.1. **Allowable stresses**

7.1.1. *Symbols*

$R_{e/t}$, yield limit, indicates the value at the calculation temperature of:

— the upper flow limit for a material presenting upper and lower flow limits,

— the 1.0 % proof strength of austenitic steel and non-alloyed aluminium,

— the 0.2 % proof strength in other cases.

$R_{m/20}$ indicates the minimum value of the ultimate tensile strength at 20 °C.

$R_{m/t}$ designates the ultimate tensile strength at the calculation temperature.

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:

— in the case of ferritic steel including normalised (normalised rolled) steel and excluding fine-grained steel and specially heat-treated steel, $\frac{2}{3}$ of $R_{e/t}$ and $\frac{5}{12}$ of $R_{m/20}$,

— in the case of austenitic steel:

— if its elongation after rupture exceeds 30 %, $\frac{2}{3}$ of $R_{e/t}$

— or, alternatively, and if its elongation after rupture exceeds 35 %, $\frac{5}{6}$ of $R_{e/t}$ and $\frac{1}{3}$ of $R_{m/t}$,

— in the case of non-alloy or low-alloy cast steel, $\frac{10}{19}$ of $R_{e/t}$ and $\frac{1}{3}$ of $R_{m/20}$,

— in the case of aluminium, $\frac{2}{3}$ of $R_{e/t}$,

— in the case of aluminium alloys excluding precipitation hardening alloys $\frac{2}{3}$ of $R_{e/t}$ and $\frac{5}{12}$ of $R_{m/20}$.

7.2. **Joint coefficients**

For welded joints, the joint coefficient shall not exceed the following values:

— for equipment subject to destructive and non-destructive tests which confirm that the whole series of joints show no significant defects: 1,

— for equipment subject to random non-destructive testing: 0.85,

— for equipment not subject to non-destructive testing other than visual inspection: 0.7.

If necessary, the type of stress and the mechanical and technological properties of the joint shall also be taken into account.

7.3. **Pressure limiting devices, particularly for pressure vessels**

The momentary pressure surge referred to in point 2.11.2 shall be kept to 10 % of the maximum allowable pressure.

7.4. **Hydrostatic test pressure**

For pressure vessels, the hydrostatic test pressure referred to in point 3.2.2 shall be no less than either of the following:

— 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,

— the maximum allowable pressure multiplied by the coefficient 1.43, whichever is the greater.

7.5. **Material characteristics**

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.

Regulation 14

SCHEDULE 2

TEXT OF ANNEX II TO THE DIRECTIVE

CONFORMITY ASSESSMENT TABLES

1. The references in the tables to categories of modules are the following:

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

2. The safety accessories defined in point 4 of Article 2 of the Directive, and referred to in Article 4(1)(*d*) of the Directive, are classified in category IV. However, by way of exception, safety accessories manufactured for specific equipment may be classified in the same category as the equipment they protect.

3. The pressure accessories defined in point 5 of Article 2 of the Directive, and referred to in Article 4(1)(*d*) of the Directive, are classified on the basis of:

— their maximum allowable pressure PS,

— their volume V or their nominal size DN, as appropriate,

— the group of fluids for which they are intended.

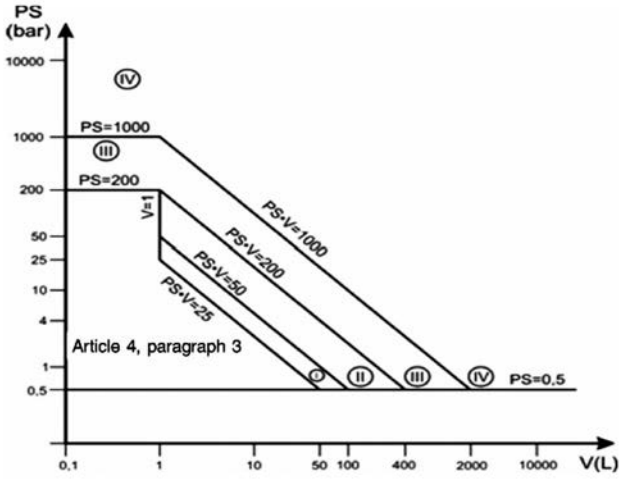
The appropriate table for vessels or piping is to be used to determine the conformity assessment category.

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.

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

Table 1

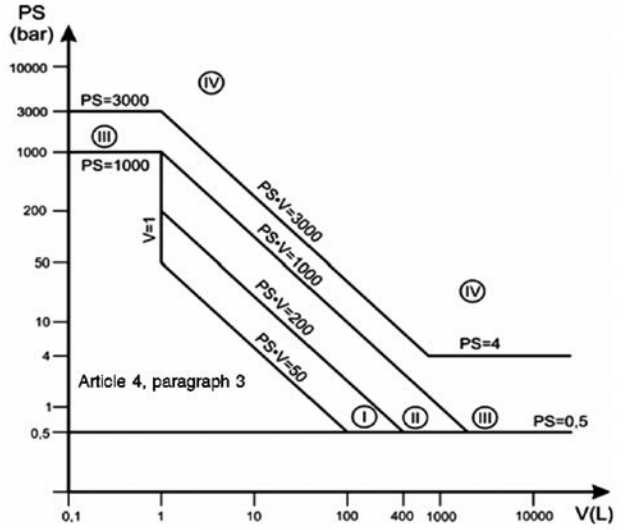
Vessels referred to in Article 4(1)(*a*)(i) of the Directive, first indent



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.

Table 2

Vessels referred to in Article 4(1)(*a*)(i) of the Directive, second indent



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

Table 3

Vessels referred to in Article 4(1)(*a*)(ii) of the Directive. first indent

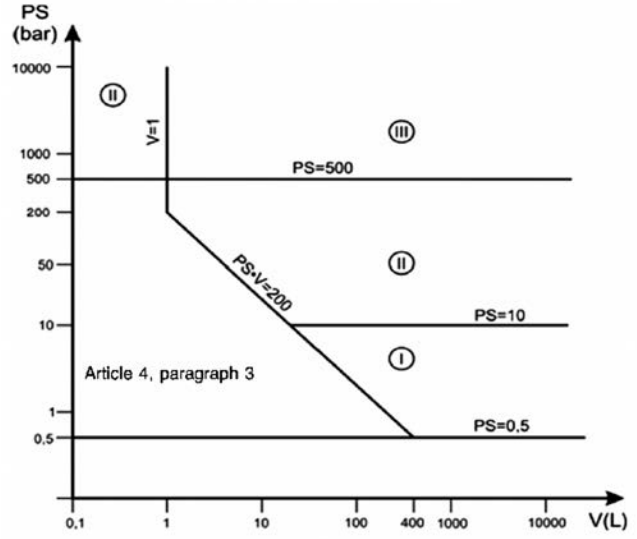
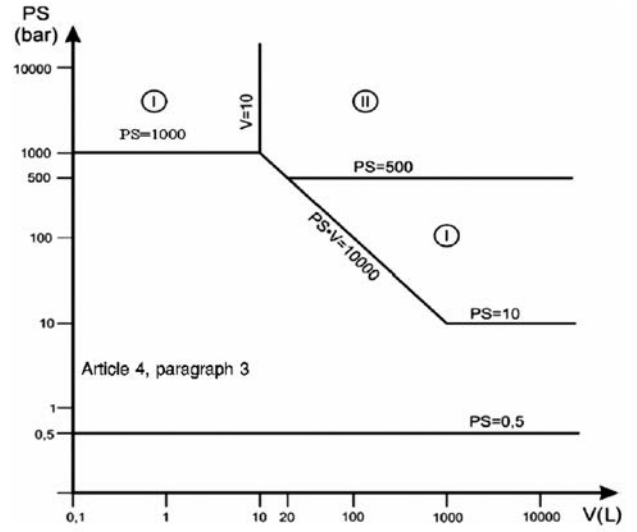


Table 4

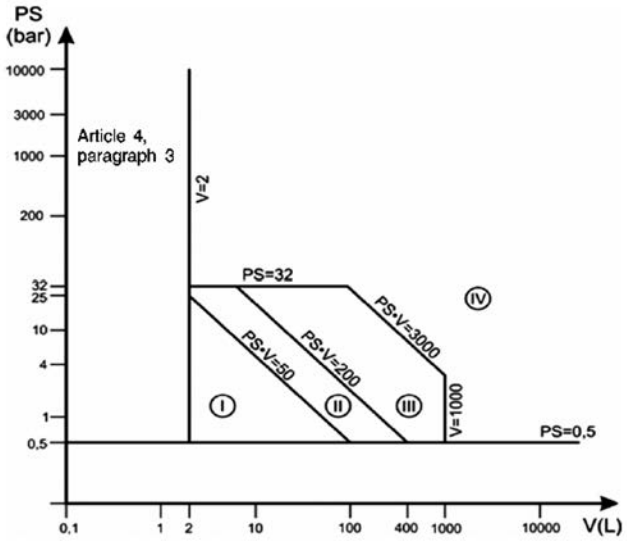
Vessels referred to in Article 4(1)(*a*)(ii) of the Directive. second indent



Exceptionally, assemblies intended for generating warm water as referred to in the second subparagraph of Article 4(2) of the Directive, 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 Schedule 1, or to full quality assurance (Module H).

Table 5

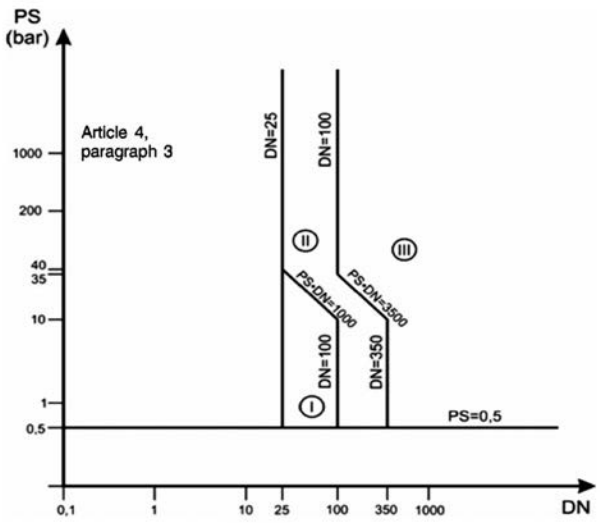
Pressure equipment referred to in Article 4(1)(*b*) of the Directive



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

Table 6

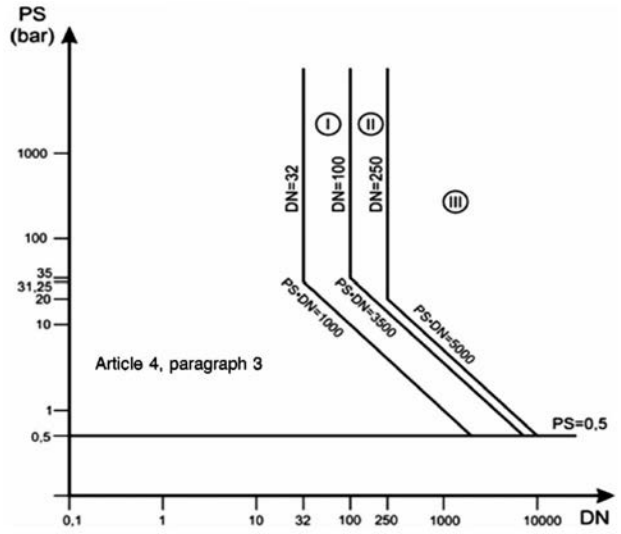
Piping referred to in Article 4(1)(*c*)(i) of the Directive, first indent



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.

Table 7

Piping referred to in Article 4(1)(*c*)(i) of the Directive, second indent



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.

Table 8

Piping referred to in Article 4(1)(*c*)(ii) of the Directive, first indent

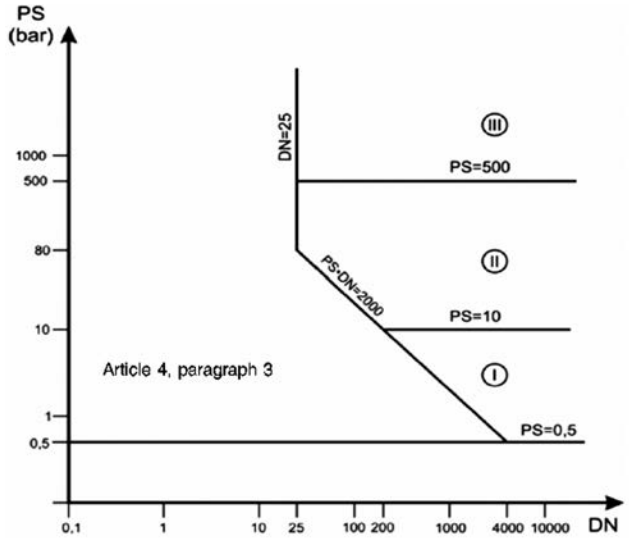
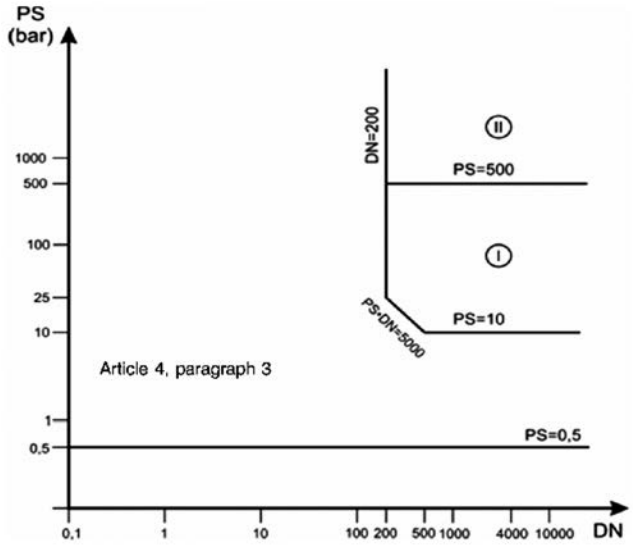


Table 9

Piping referred to in Article 4(1)(*c*)(ii) of the Directive, second indent



Regulations 7, 17 and 19

SCHEDULE 3

TEXT OF ANNEX III to Directive 2014/68/EU

CONFORMITY ASSESSMENT PROCEDURES

The obligations arising from the provisions on pressure equipment in this Schedule also apply to assemblies.

1. MODULE A: (INTERNAL PRODUCTION CONTROL)

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 the Directive.

2. **Technical documentation**

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:

— a general description of the pressure equipment,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,

— 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 the 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,

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

— test reports.

3. **Manufacturing**

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 the Directive.

4. **CE marking and EU declaration of conformity**

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

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.

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

5. **Authorised representative**

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.

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

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 the Directive.

2. **Technical documentation**

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:

— a general description of the pressure equipment,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

— 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 the 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,

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

— test reports.

3. **Manufacturing**

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 the Directive that apply to it.

4. **Final assessment and pressure equipment checks**

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.

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.

During its unexpected visits, the notified body shall:

— establish that the manufacturer actually performs final assessment in accordance with point 3.2 of Schedule 1.

— 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.

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.

Should one or more of the items of pressure equipment or assembly not conform, the notified body shall take appropriate measures.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. **CE marking and EU declaration of conformity**

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

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.

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

6. **Authorised representative**

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.

3. MODULE B: EU-TYPE EXAMINATION

3.1. *EU-Type examination — production type*

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 the Directive.

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.

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— 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:

  — a general description of the pressure equipment,

  — conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

  — descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

  — 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 the 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,

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

  — test reports,

— information concerning the tests provided for in manufacture,

— information concerning the qualifications or approvals required under points 3.1.2 and 3.1.3 of Schedule 1,

— the specimens representative of the production envisaged.

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

The notified body may request further specimens if needed for carrying out the test programme;

— 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.

4. The notified body shall:

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.

In particular, the notified body shall:

— 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 Schedule 1,

— 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 Schedule 1,

— 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 Schedule 1.

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.

4.3. 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.

4.4. 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 the Directive.

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

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.

6. Where the type meets the requirements of the 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.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

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.

Where the type does not satisfy the applicable requirements of the 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.

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 the Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

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 the 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.

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.

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.

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.

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.

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.

3.2. ***EU-Type examination — design type***

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 the Directive.

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.

The experimental design method provided for in point 2.2.4 of Schedule 1 shall not be used in the context of this module.

3. The manufacturer shall lodge an application for EU-type examination — design type with a single notified body of his choice.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— 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:

— a general description of the pressure equipment,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

— 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 the 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,

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

— information regarding the qualifications or approvals required under points 3.1.2 and 3.1.3 of Schedule 1,

— 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.

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

4. The notified body shall:

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

In particular, the notified body shall:

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

— 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 Schedule 1.

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.

4.3. 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 the Directive.

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.

6. Where the design meets the requirements of the 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.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

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.

Where the design does not satisfy the applicable requirements of the 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.

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 the Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

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 the 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.

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.

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.

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.

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.

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.

4. MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS

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 the Directive that apply to it.

2. **Manufacturing**

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 the Directive that apply to them.

3. **Final assessment and pressure equipment checks**

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.

The notified body shall establish that the manufacturer actually performs final assessment in accordance with point 3.2 of Schedule 1.

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 the Directive.

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.

Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

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.

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.

4. **CE marking and EU declaration of conformity**

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 the Directive.

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. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

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

5. Authorised representative

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.

5. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

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 the Directive that apply to it.

2. **Manufacturing**

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.

3. **Quality system**

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.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information on the pressure equipment type envisaged,

— the documentation concerning the quality system,

— the technical documentation of the approved type and a copy of the EU-type examination certificate.

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 the Directive that apply to it.

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.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,

— 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 Schedule 1,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— 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 Schedule 1, etc., and

— the means of monitoring the achievement of the required quality and the effective operation of the quality system.

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.

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 the Directive. The audit shall include an inspection visit to the manufacturer's premises.

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 the Directive and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

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.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. 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:

— the quality system documentation,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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.

4.4. 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:

— the category of the pressure equipment,

— the results of previous surveillance visits,

— the need to follow up corrective actions,

— special conditions linked to the approval of the system, where applicable,

— significant changes in manufacturing organisation, policy or techniques.

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.

5. **CE marking and EU declaration of conformity**

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 the Directive.

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.

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

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:

— the documentation referred to point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.3, 3.5, 4.3 and 4.4.

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.

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.

8. **Authorised representative**

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.

6. MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS

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 the Directive that apply to it.

2. **Technical documentation**

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:

— a general description of the pressure equipment,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,

— 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 the 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,

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

— test reports.

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.

4. **Manufacturing**

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.

5. **Quality system**

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.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information on the pressure equipment type envisaged,

— the documentation concerning the quality system,

— the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the pressure equipment with the requirements of the Directive that apply to it.

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.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,

— 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 Schedule 1,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— 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 Schedule 1, etc.,

— the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

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.

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 the Directive. The audit shall include an assessment visit to the manufacturer's premises.

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 the Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

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.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. **Surveillance under the responsibility of the notified body**

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. 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:

— the quality system documentation,

— the technical documentation referred to in point 2,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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.

6.4. 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:

— the category of the pressure equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action(*s*),

— special conditions linked to the approval of the system, where applicable,

— significant changes in manufacturing organisation, policy or techniques.

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.

7. **CE marking and EU declaration of conformity**

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 the Directive.

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.

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

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:

— the documentation referred to in point 5.1,

— the change referred to in point 5.5,

— the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.

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.

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.

10. **Authorised representative**

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.

7. MODULE E: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT QUALITY ASSURANCE

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 the Directive that apply to it.

2. **Manufacturing**

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.

3. **Quality system**

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.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information on the pressure equipment type envisaged,

— the documentation concerning the quality system,

— the technical documentation of the approved type and a copy of the EU-type examination certificate.

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 the Directive.

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.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

— the examinations and tests that will be carried out after manufacture,

— 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 Schedule 1,

— the means of monitoring the effective operation of the quality system.

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.

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 the Directive. The audit shall include an assessment visit to the manufacturer's premises.

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 the Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

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.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. 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:

— the quality system documentation,

— the technical documentation,

— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

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.

4.4. 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:

— the category of the pressure equipment,

— the results of previous surveillance visits,

— the need to follow up corrective actions,

— special conditions linked to the approval of the system, where applicable,

— significant changes in manufacturing organisation, policy or techniques.

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.

5. **CE marking and EU declaration of conformity**

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 the Directive.

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.

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

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:

— the documentation referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports from the notified body which are referred to in points 3.3, 3.5, 4.3 and 4.4.

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.

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.

8. **Authorised representative**

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.

8. MODULE E1: QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING

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 the Directive that apply to it.

2. **Technical documentation**

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:

— a general description of the pressure equipment,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

— 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 the 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,

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

— test reports.

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.

4. **Manufacturing**

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.

5. **Quality system**

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.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information on the pressure equipment type envisaged,

— the documentation concerning the quality system, and

— the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the pressure equipment with the requirements of the Directive that apply to it.

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 of the Directive, or equivalent tests, and particularly final assessment as referred to in point 3.2 of Schedule 1, shall be carried out in order to ensure its conformity with the requirements of the Directive which apply to it.

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.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,

— the procedures used for the permanent joining of parts as approved in accordance with point 3.1.2 of Schedule 1,

— the examinations and tests that will be carried out after manufacture,

— 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 Schedule 1,

— the means of monitoring the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

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.

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 the Directive. The audit shall include an assessment visit to the manufacturer's premises.

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 the Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

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.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. **Surveillance under the responsibility of the notified body**

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. 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:

— the quality system documentation,

— the technical documentation referred to in point 2,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

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.

6.4. 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:

— the category of the equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action(*s*),

— special conditions linked to the approval of the system, where applicable,

— significant changes in manufacturing organisation, policy or techniques.

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.

7. **CE marking and EU declaration of conformity**

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 the Directive.

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.

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

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:

— the documentation referred to in point 5.1,

— the change referred to in point 5.5, as approved,

— the decisions and reports of the notified body referred to in points 5.3, 5.5, 6.3 and 6.4.

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.

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.

10. **Authorised representative**

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.

9. MODULE F: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT VERIFICATION

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 the Directive which apply to it.

2. **Manufacturing**

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 the Directive which apply to them.

3. **Verification**

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 the Directive.

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.

4. **Verification of conformity by examination and testing of every item of pressure equipment**

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 the Directive. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

In particular, the notified body shall:

— 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 Schedule 1,

— verify the certificate issued by the materials manufacturer in accordance with point 4.3 of Schedule 1,

— carry out or have carried out the final inspection and proof test referred to in point 3.2 of Schedule 1 and examine the safety devices, if applicable.

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.

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.

5. **CE marking and EU declaration of conformity**

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 the Directive.

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.

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

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.

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.

7. **Authorised representative**

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.

10. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

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 the Directive that apply to it.

2. **Technical documentation**

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4.

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, wherever applicable, contain at least the following elements:

— a general description of the pressure equipment,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,

— 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 the 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,

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

— test reports,

— 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 Schedule 1.

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. **Manufacturing**

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 the Directive.

4. **Verification**

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 the 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.

In particular the notified body shall:

— examine the technical documentation with respect to the design and the manufacturing procedures,

— 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 Schedule 1,

— 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 Schedule 1,

— verify the qualifications or approvals required under points 3.1.2 and 3.1.3 of Schedule 1,

— carry out the final inspection referred to in point 3.2.1 of Schedule 1, perform or have performed the proof test referred to in point 3.2.2 of Schedule 1, and examine the safety devices, if applicable.

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.

5. **CE marking and EU declaration of conformity**

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 the Directive.

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.

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

6. **Authorised representative**

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.

11. MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE

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 the Directive that apply to it.

2. **Manufacturing**

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.

3. **Quality system**

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.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— the technical documentation for one model of each type of pressure equipment intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:

  — a general description of the pressure equipment,

  — conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

  — descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

  — 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 the 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,

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

— test reports,

— the documentation concerning the quality system, and

— a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the pressure equipment with the requirements of the Directive that apply to it.

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.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,

— 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 the Directive that apply to the pressure equipment will be met,

— 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 Schedule 1,

— 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 Schedule 1,

— the examinations and tests to be carried out before, during, and after manufacture, and the frequency with which they will be carried out,

— 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 Schedule 1, etc.,

— the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

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.

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 the Directive. The audit shall include an assessment visit to the manufacturer's premises.

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 the Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

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.

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.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

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.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. 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:

— the quality system documentation,

— the quality records provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— 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.

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.

4.4. 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:

— the category of the equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action(*s*),

— special conditions linked to the approval of the system, where applicable,

— significant changes in manufacturing organisation, policy or techniques.

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.

5. **CE marking and EU declaration of conformity**

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 item of pressure equipment that satisfies the applicable requirements of the Directive.

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.

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

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:

— the technical documentation referred to in point 3.1,

— the documentation concerning the quality system referred to in point 3.1,

— the change referred to point 3.4, as approved,

— the decisions and reports of the notified body referred to in points 3.3, 3.4, 4.3 and 4.4.

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.

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.

8. **Authorised representative**

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.

12. MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

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.

2. **Manufacturing**

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. The adequacy of the technical design of the pressure equipment shall have been examined in accordance with point 4.

3. **Quality system**

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.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— the technical documentation for one model of each type of pressure equipment intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:

  — a general description of the pressure equipment,

  — conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

  — descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

  — 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 the 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,

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

  — test reports,

— the documentation concerning the quality system,

— a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the pressure equipment with the requirements of the Directive that apply to it.

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.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,

— 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,

— 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 Schedule 1,

— 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 Schedule 1,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— 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 Schedule 1, etc.,

— the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

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. 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 the Directive. The audit shall include an assessment visit to the manufacturer's premises.

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 the Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

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.

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.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

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.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

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.

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.

4. **Design examination**

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.

4.2. 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 the Directive that apply to it. It shall include:

— the name and address of the manufacturer,

— a written declaration that the same application has not been lodged with any other notified body,

— 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 and operation of the pressure equipment. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the pressure equipment,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

— 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 the 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,

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

— test reports,

— 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.

4.3. The notified body shall examine the application, and where the design meets the requirements of the 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.

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.

Where the design does not satisfy the applicable requirements of the Directive, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

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 the Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

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 the 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.

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.

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.

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.

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.

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.

5. **Surveillance under the responsibility of the notified body**

5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

5.2. 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:

— the quality system documentation,

— the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— 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.

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.

5.4. 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 must be considered in the visit control system:

— the category of the equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action(*s*),

— special conditions linked to the approval of the system, where applicable,

— significant changes in manufacturing organisation, policy or techniques.

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.

5.5. Special surveillance of the final assessment

Final assessment as referred to in section 3.2 of Schedule 1 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.

It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

6. **CE marking and EU declaration of conformity**

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 the Directive.

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.

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

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:

— the documentation concerning the quality system referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

8. **Authorised representative**

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.

Regulation 19

SCHEDULE 4

TEXT OF ANNEX IV THE DIRECTIVE

EU DECLARATION OF CONFORMITY (No XXXX)[5]

1. Pressure equipment or assembly (product, type, batch or serial number):

2. Name and address of the manufacturer and, where applicable, his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

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):

   — description of the pressure equipment or assembly,

   — conformity assessment procedure followed,

   — in the case of assemblies, description of the pressure equipment constituting the assembly, and the conformity assessment procedures followed,

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

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.

8. Additional information:

   Signed for and on behalf of:

   (place and date of issue):

   (name, function) (signature):

   (where appropriate, particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative)

[5]It is optional for the manufacturer to assign a number to the declaration of conformity

Regulation 2

SCHEDULE 5

TEXT OF ANNEX VI TO THE DIRECTIVE CORRELATION TABLE

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L.S.

Given under my Official Seal,
26 May 2017.

MARY MITCHELL O'CONNOR,
Minister for Jobs, Enterprise and Innovation.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations transpose into national legislation the provisions of Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 setting out the requirements for the making available on the market and putting into service, as well as the essential health and safety requirements relating to the design and construction of pressure equipment. These Regulations also set out the obligations on economic operators in relation to these products and the required conformity assessment for such products. These Regulations also give further effective to 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 and include duties to have proper market surveillance procedures consistent with EU Regulation 765/2008.

These Regulations do not impede the making available on the market of products covered by Directive 97/23/EC which are in conformity with that Directive and which were placed on the market before 1 June 2015.

The Regulations revoke and replace the European Communities (Pressure Equipment) Regulations (S.I.No.400 of 1999).

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52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)
nó trí aon díoltóir leabhar.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

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ISBN 978-1-4064-5915-9

€24.38

9 781406 459159

Wt. (B32777). 305. 6/17. Essentra. Gr 30-15.