

TRANSPOSITION NOTE

Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the member States relating to the making available on the market of pressure equipment.

1. This Transposition Note has been prepared by the UK's Department for Business, Energy and Industrial Strategy and is intended to explain how the 2014 Directive is implemented in the UK.
2. This instrument is being made in order to implement the provisions of the revised EU Pressure Equipment Directive ("PED") (2014/68/EU), the majority of the provisions of which came into force by 18 July 2016.
3. This instrument will replace and repeal the current Regulations (the Pressure Equipment Regulations 1999, S.I. 1999/2001) as amended.
4. One provision of the PED was required to be transposed by 1 June 2015 and was implemented by means of S.I. 2015/399 which amended S.I.1999/2001. That amendment has been incorporated into this instrument.
5. The Regulations do not go beyond what is necessary to implement the 2014 Directive.
6. The Secretary of State is responsible for taking measures to implement the 2014 Directive.

TRANSPOSITION OF DIRECTIVE 2014/68/EU

Article	Objective of the Article	Implementation
	The Directive shall apply to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar	Regulation 3(1)) of the Pressure Equipment (Safety) Regulations 2016
1(2)	Exclusions from scope	Regulation 4(1) and Schedule 1
2	Definitions	Regulation 2
3(1)	Requirement on Member States to take all appropriate measures to ensure that pressure equipment and assemblies may be made available on the market and put into service only if they satisfy the requirements of the Directive when properly installed and maintained and used for the purpose they were intended.	Implemented by the obligations on economic operators in Part 2 of the Regulations This obligation is imposed by the obligations on manufacturers in Article 6(1), which have been transposed

3(2)	This shall not affect Member States' entitlement to lay down requirements for the protection of workers during use of the equipment	No requirement to transpose by these Regulations
3(3)	Member States shall not prevent the showing of equipment or assemblies at trade fairs, exhibitions etc provided a visible sign indicates such equipment shall not be placed on the market until it has been brought in conformity, and appropriate safety measures taken in accordance with any requirements laid down by the competent authority	Regulation 5
4(1)	Pressure equipment which must satisfy essential safety requirements	Regulation 6
4(2)	Assemblies which must satisfy the essential safety requirements	Regulation 7
4(3)	Pressure equipment and assemblies which must be designed and manufactured in accordance with sound engineering practice	Regulation 8
5(1)	Obligation not to impede the making available of pressure equipment or assemblies complying with the Directive	Unnecessary to implement this explicitly.
5(2)	Where a user inspectorate has been designated it may not restrict the placing on the market of equipment assessed as in conformity by a user inspectorate in another Member State	Unnecessary to implement this explicitly.
5(3)	Member States may require information to be provided in the official languages of the Union determined by the Member State in which equipment is made available.	Not necessary to implement this specifically as it is a discretionary provision.
6(1)	Obligation to ensure: (i) design and manufacture of pressure equipment or assemblies referred to in Article 4(1) and (2) is in accordance with essential safety requirements; (ii) design and manufacture of pressure equipment and assemblies referred to in Article 4(3) is in accordance with sound engineering practice	(i) Regulation 9(1) (ii) Regulation 9(2)
6(2)	For pressure equipment and assemblies referred to in Art 4(1) and (2), obligation to draw up technical documentation, declaration of conformity and affix CE marking	Regulation 10, 11
6(3)	Requirement for retention of technical documentation and declaration of conformity for 10 years	Regulation 12
6(4) para 1	Obligation to ensure procedures for series production to remain in conformity.	Regulation 15
6(4) para 2	Requirement to carry out sample testing and monitoring	Regulation 16
6(5)	Requirement to ensure proper labelling and numbering to allow for identification	Regulation 13(1)(a) and 13(2)
6(6)	Requirement to indicate name, trade name or trade	Regulation 13(1)(b)

	mark and address and contact details must be in a language easily understood by end-users and market surveillance authorities	13(2) and 13(3)
6(7)	Manufacturers must ensure that a pressure equipment or assemblies are accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users as determined by the Member State concerned, and to be clear, understandable and intelligible	Regulation 14
6(8)	<u>Obligation 1:</u> Manufacturers who consider or have reason to believe that they have placed on the market equipment not in conformity with the Directive must immediately take corrective action to bring that equipment into conformity, to withdraw it or recall it. <u>Obligation 2:</u> Where pressure equipment or an assembly presents a risk, manufacturers must immediately inform the competent national authorities of the Member States in which the article has been made available to that effect, giving details of the non-compliance and any corrective measures taken.	Regulation 17
6(9)	Manufacturers must, further to a reasoned request from a competent national authority, provide it with information and documentation to demonstrate conformity with the Directive, in a language which can be easily understood, and cooperate with the authority on any action to eliminate risks posed by pressure equipment or assemblies	Regulation 18
7(1)	A manufacturer may appoint an authorised representative by written mandate. Key obligations to ensure conformity and draw up technical documentation must not be delegated to the authorised representative	Regulation 19(1), (3)
7(2)	Obligations on authorised representative to perform tasks and requirements for mandate	Regulation 19(2)
8(1)	Importers must only place compliant pressure equipment or assemblies on the market	Regulation 17
8(2)	<u>Obligation 1:</u> Importers of pressure equipment or assemblies within Article 4(1) and (2) must ensure conformity assessment procedure has been carried out, and check technical documentation, markings, required documents. <u>Obligation 2:</u> An importer of Article 4(3) equipment must ensure technical requirements have been complied with. <u>Obligation 3:</u> Where an importer considers pressure equipment or an assembly is not in conformity he must not place it on the market, and where it presents a risk the importer must inform the manufacturer and market surveillance authority	Regulation 21 Regulation 22

8(3)	Importers must indicate their name and address on the equipment or a document accompanying the equipment in a language easily understood by consumers, other users and market surveillance authorities.	Regulation 23
8(4)	Importers must ensure equipment is accompanied by instructions and safety information in a language easily understood by consumers and other users as determined by the Member State	Regulation 24(1)
8(5)	Importers must ensure that while pressure equipment or assemblies are under their responsibility, their storage and transport do not jeopardise their compliance with the essential safety requirements.	Regulation 25
8(6)	<u>Obligation 1:</u> When deemed appropriate with regard to the risks presented by pressure equipment or assemblies, importers must carry out certain monitoring activities and keep a register. <u>Obligation 2:</u> Importers must keep distributors informed of monitoring activities.	Regulation 26
8(7)	<u>Obligation 1:</u> Importers who consider or have reason to believe that they have placed on the market equipment not in conformity with the Directive must immediately take corrective action to bring that equipment into conformity, to withdraw it or recall it. <u>Obligation 2:</u> Where equipment presents a risk, importers must immediately inform the competent national authorities of the Member States in which the equipment has been made available to that effect, giving details of the non-compliance and any corrective measures taken	Regulation 27
8(8)	Importers must keep the technical documentation and the EU declaration of conformity for 10 years after the equipment is placed on the market.	Regulation 28
8(9)	<u>Obligation 1:</u> Importers must, further to a reasoned request, provide a competent national authority with information and documentation necessary to demonstrate the conformity of equipment with the Directive in a language which can be easily understood by the market surveillance authority. <u>Obligation 2:</u> Importers must cooperate with the authority on action taken to eliminate risks posed by equipment placed on the market.	Regulation 29
9(1)	When making pressure equipment or assemblies available on the market, distributors must act with due care in relation to the requirements of the Directive.	Regulation 30
9(2)	<u>Obligation 1:</u> Before a distributor makes equipment or	<u>Obligation 1:</u> Regulation

	<p>assemblies referred to in Article 4(1) and (2) available on the market, he must ensure that the manufacturer and importer have satisfied certain obligations and that the equipment is accompanied by the required documents in a language which can be easily understood by consumers and other users in the member State concerned.</p> <p><u>Obligation 2:</u> Where a distributor considers, or has reason to believe, that equipment is not in conformity with the essential safety requirements he must not make it available on the market.</p> <p><u>Obligation 3:</u> Where the equipment presents a risk, the distributor must inform the manufacturer or the importer and the market surveillance authorities.</p>	<p>31</p> <p><u>Obligation 2:</u> Regulation 33(1)</p> <p><u>Obligation 3:</u> Regulation 33(2)</p>
9(3)	Distributors must ensure that while pressure equipment or an assembly is under their responsibility, they do not jeopardise its compliance with the essential safety requirements.	Regulation 32
9(4)	<p><u>Obligation 1:</u> Distributors who consider, or have reason to believe, that equipment which they have made available on the market is not in conformity must make sure that corrective measures are taken to bring that article into conformity, withdraw it or recall it.</p> <p><u>Obligation 2:</u> Where the equipment presents a risk, the distributor must immediately inform the competent national authorities of the Member States in which they made the equipment available.</p>	<p><u>Obligation 1:</u> Regulation 33(1)</p> <p><u>Obligation 2:</u> Regulation 33(2)</p>
9(5)	<p><u>Obligation 1:</u> Distributors must, further to a reasoned request, provide a competent national authority with information and documentation necessary to demonstrate the conformity of pressure equipment or assemblies with the Directive</p> <p><u>Obligation 2:</u> Distributors must cooperate with the authority on action taken to eliminate risks posed by equipment made available on the market.</p>	Regulation 35(1), 35(3)(b)
10	Importers and distributors to be treated as manufacturers where they place pressure equipment or assemblies on the market under their name or modify them in a way that affects their compliance with the Directive.	Regulation 36
11	Economic operators must, on request identify other economic operators in the supply chain. They must be able to do this for 10 years after the supply of pressure equipment or assemblies.	Regulation 38
12(1)	Pressure equipment or assemblies are presumed to be in conformity with the essential safety requirements to	Regulation 40(1)

	the extent that they are in conformity with a harmonised standard covering those requirements.	
12(2)	The materials used in the manufacture of pressure equipment or assemblies in conformity with European approval for materials, the references to which have been published in the Official Journal, are to be presumed to be in conformity with the applicable essential safety requirements	Reg 40(2)
13	Pressure equipment must be classified by category in accordance with Annex II. Fluids to be divided into two groups for the purposes of classification. Where a vessel is composed of a number of chambers or containing a number of fluids it shall be classified on the basis of the highest category	Reg 41, Schedule 3
14(1)	Conformity assessment procedure is to be determined by the category in which the equipment is classified.	Reg 42(1)
14(2)	Applicable conformity assessment procedures	Reg 42(1)
14(3)	Equipment is to be subject to one of the conformity assessment procedures from those laid down for the relevant category. Manufacturer may choose to apply a procedure applicable to a higher category.	Reg 42(1), 42(2)
14(4)	In certain quality assurance frameworks the notified body must take a sample of equipment; it must carry out at least two visits during the first year of manufacture and subsequent visits as determined on the basis of relevant criteria.	Reg 43
14(5)	For one-off production of vessels and equipment in certain cases, the notified body must perform the final assessment	Reg 44
14(6)	Assemblies must be subject to a global conformity assessment procedure comprising certain specified assessments	Reg 45
14(7)	Competent authorities may allow the making available on the market or putting into service equipment and assemblies to which the procedures have not been applied in the interests of experimentation	Reg 46
14(8)	Records and correspondence relating to conformity assessment procedures must be drafted in an official language of the Member State where the conformity assessment body is established or a language accepted by that body.	Reg 47
15(1)	European approval for materials is to be issued by a designated notified body	Reg 50(1), 50(2)
15(2)	Before issuing a European approval for materials the notified body must notify the Member States and the Commission	Reg 50(5)
15(3)	A copy of the European approval for materials must be sent to the Member States, notified bodies and the Commission	Reg 55(7)

15(4)	Where the European approval for materials satisfies the requirements, the references of it must be published by the Commission	This is an obligation on the Commission
15(5)	The notified body which issued the European approval for materials must withdraw it if it finds it should not have been issued or it is covered by a harmonised standard, and inform other Member States, notified bodies and the Commission	Reg 55(8), (9)
15(6)	When a Member State or Commission considers a European approval for materials does not satisfy the essential safety requirements , the Commission must decide whether to withdraw the references of it from the Official Journal	This is an obligation on the Commission
16(1)	Member States may authorise the placing on the market or putting into service of equipment whose conformity has been assessed by a designated user inspectorate.	Part 3 of the Regulations This discretion is implemented by the application of the conformity assessment parts of the Regulations to assessment by user inspectorates.
16(2)	Pressure equipment and assemblies whose conformity has been assessed by a user inspectorate must not bear the CE marking.	Regulation 39(2)
16(3)	Equipment assessed by a user inspectorate may be used only in establishments operated by the group of which the inspectorate is part and a common safety policy must be applied.	Regulation 58(7)
16(4)	The user inspectorate shall act exclusively for the group of which it is part.	Regulation 58(6)
16(5)	The conformity assessment procedures applicable by user inspectorates	Regulation 58(4)
16(6)	Member States must notify other Member States and Commission of the user inspectorates they have authorised and the relevant tasks and establishments.	Regulation 59(a)
16(7)	In designating user inspectorates the Member States must apply the relevant requirements	Regulation 58(3), 58(5), Schedule 5
17(1)	The EU declaration of conformity must state that the fulfilment of the essential safety requirements has been demonstrated	Regulation 48
17(2)	<u>Obligation 1:</u> The EU declaration of conformity must have the model structure set out in Annex IV of the Directive. <u>Obligation 2:</u> The EU declaration of conformity must contain the elements specified in the relevant procedures set out in Annex III of the Directive. <u>Obligation 3:</u> The EU declaration of conformity must be continuously updated.	<u>Obligation 1:</u> Regulation 48(c) <u>Obligation 2:</u> Regulation 48(b) <u>Obligation 3:</u> Regulation 11(3)

	<u>Obligation 4</u> : The EU declaration of conformity must be translated into the language required by the Member State in which the pressure equipment or assembly is placed or made available on the market.	<u>Obligation 4</u> : Regulation 37
17(3)	Where pressure equipment or an assembly is subject to more than one Union act requiring an EU declaration of conformity, a single declaration must be drawn up. The declaration must contain the identification of the Union acts concerned.	Regulation 11(4)
17(4)	By drawing up the EU declaration of conformity, the manufacturer assumes responsibility for the compliance of the pressure equipment or assembly with the requirements of the Directive	It is unnecessary to implement this requirement.
18	The CE marking is subject to the general principles in Article 30 of Regulation (EC) No 765/2008	Regulation 39 This obligation has been implemented by setting out the principles contained in Article 30 of Regulation (EC) No 765/2008 as enforceable prohibitions.
19(1)	The CE marking must be affixed visibly, legibly and indelibly to the pressure equipment or assembly or to its data plate; or to its packaging	Regulation 49(1), 49(3), 49(4)
19(2)	Individual items of pressure equipment making up an assembly shall continue to bear the marking	Regulation 49(5)
19(3)	The CE marking must be affixed before the pressure equipment or assembly is placed on the market.	Regulation 11(1)(b)
19(4)	The CE marking must be followed by the identification number of the notified body, where that body is involved in the production control phase. The identification number must be affixed by the body itself, or under its instruction, by the manufacturer.	Regulation 49(6), 49(7)
19(5)	The CE marking may be followed by any other mark indicating a special risk or use	Regulation 49(8)
19(6)	Member States must build on existing mechanisms to ensure correct application of the regime governing CE marking and must take appropriate action in the event of improper use.	Regulation 39 This provision requires action, but does not specify the action that must be taken. The UK implements this obligation by prohibiting the improper use of the CE marking, and in particular by enforcing the requirements set out

		in Article 30 of Regulation (EC) 765/2008.
Article 20	Member States must notify the Commission and other Member States of notified bodies, user inspectorates and recognised third party organisations authorised to carry out conformity assessment tasks.	Regulations 51, 52, 53 and 55(1)
21(1)	Member States must designate a notifying authority which is to be responsible for assessment and notification of conformity assessment bodies and the monitoring of notified bodies, recognised third party organisations and user inspectorates.	The Secretary of State will be the notifying authority so no implementation is required.
21(2)	Member States may decide that the assessment and monitoring is to be carried out by a national accreditation body.	Regulation 61
21(3)	Where such a body is not a government entity it must be a legal entity and have arrangements to cover liabilities	Regulation 61
21(4)	The notifying authority shall take responsibility for tasks performed by the body.	Not necessary to implement this in the legislation
22(1)	A notifying authority must be established in such a way that no conflict of interest with conformity assessment bodies occurs	It is not necessary to implement this explicitly.
22(2)	A notifying authority must be organised and operated so as to safeguard the objectivity and impartiality of its activities.	It is not necessary to implement this explicitly.
22(3)	A notifying authority must be organised so that each decision on notification is taken by competent persons, different from those who carried out the assessment	It is not necessary to implement this explicitly.
22(4)	A notifying authority must not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.	It is not necessary to implement this explicitly.
22(5)	A notifying authority must safeguard the confidentiality of the information it obtains.	It is not necessary to implement this explicitly.
22(6)	A notifying authority must have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.	It is not necessary to implement this explicitly.
23	Member States must inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies.	Regulation 60(2) The requirement to inform the Commission of procedures for assessment and notification is satisfied by notifying the Regulations.
24(1)	For the purposes of notification, a notified body or recognised third party organisation must meet the requirements in paragraphs 2 to 11.	Regulation 55(1)(a) and (b), Schedule 4

24(2)	A conformity assessment must be established under the national law of a Member State and have legal personality.	Schedule 4, paragraph 2
24(3)	A conformity assessment body must be third-party body independent of the organisation or the equipment it assesses	Schedule 4, paragraph 3
24(4)	<p><u>Obligation 1:</u> A conformity assessment body, its top level management and the personnel responsible for carrying out conformity assessment tasks must not be the designer, manufacturer, supplier, owner etc. of the equipment.</p> <p><u>Obligation 2:</u> A conformity assessment body, its top level management and the personnel responsible for carrying out conformity assessment tasks must not be directly involved in the design, manufacture, marketing etc. of the pressure equipment or assembly. They must not engage in any activity which may conflict with their independence or integrity.</p> <p><u>Obligation 3:</u> Conformity assessment bodies must ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.</p>	<p><u>Obligation 1:</u> Schedule 4, paragraph 4</p> <p><u>Obligation 2:</u> Schedule 4, paragraphs 5 and 6</p> <p><u>Obligation 3:</u> Schedule 4, paragraph 7</p>
24(5)	Conformity assessment bodies must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence and must be free from pressures and inducements which might influence their judgement.	Schedule 4, paragraph 8
24(6)	<p><u>Obligation 1:</u> A conformity assessment body must be capable of carrying out the conformity assessment tasks assigned to it and in relation to which it has been notified.</p> <p><u>Obligation 2:</u> A conformity assessment body must have at its disposal: (a) personnel with technical knowledge and sufficient experience; (b) the descriptions of procedures in accordance with which conformity assessment is carried out; (c) the procedure for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, the degree of complexity of the product technology etc.</p> <p><u>Obligation 3:</u> A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner.</p>	<p><u>Obligation 1:</u> Schedule 4, paragraph 9</p> <p><u>Obligation 2:</u> Schedule 4, paragraph 10</p> <p><u>Obligation 3:</u> Schedule 4, paragraph 11</p>

24(7)	The personnel responsible for carrying out conformity assessment tasks must have: (a) sound technical and vocational training covering all the relevant conformity assessment activities; (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority; (c) appropriate knowledge and understanding of the essential safety requirements, the relevant harmonised standards and legislation; (d) the ability to draw up certificates, records and reports.	Schedule 4, paragraph 12
24(8)	<u>Obligation 1:</u> The impartiality of the conformity assessment bodies, their top level management and the personnel responsible for carrying out conformity assessment tasks must be guaranteed. <u>Obligation 2:</u> The remuneration of the top level management and personnel responsible for carrying out conformity assessment tasks must not depend on the number of assessments carried out or on the results of the assessments.	<u>Obligation 1:</u> Schedule 4, paragraph 13 <u>Obligation 2:</u> Schedule 4, paragraph 14
24(9)	Conformity assessment bodies must take out liability insurance unless liability is assumed by the State or the Member State is responsible for the conformity assessment.	Schedule 4, paragraph 15
24(10)	<u>Obligation 1:</u> The personnel of a conformity assessment body must observe professional secrecy, except in relation to the competent authorities of the Member State in which it is carrying out its activities. <u>Obligation 2:</u> Proprietary rights must be protected.	<u>Obligation 1:</u> Schedule 4, paragraphs 16 and 17 <u>Obligation 2:</u> Schedule 4, paragraph 16
24(11)	Conformity assessment bodies must participate in, or ensure that their personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group and must apply as general guidance the administrative decisions and documents produced by that group.	Schedule 4, paragraph 18
25(1)	For the purposes of notification, a user inspectorate must meet the requirements in paragraphs 2 to 11.	Regulation 55(1)(c), 58(3)
25(2)	A user inspectorate must be established under the national law of a Member State and have legal personality.	Schedule 5, para 1
25(3)	A user inspectorate must be organisationally identifiable and have reporting methods to demonstrate its impartiality	Schedule 5 para 2
25(4)	<u>Obligation 1:</u> A user inspectorate, its top level management and the personnel responsible for carrying out conformity assessment tasks must not be the designer, manufacturer, supplier, owner etc. of the equipment.	Schedule 5 paras 3, 4, 5

	<p><u>Obligation 2:</u> A user inspectorate, its top level management and the personnel responsible for carrying out conformity assessment tasks must not be directly involved in the design, manufacture, marketing etc. of the pressure equipment or assembly. They must not engage in any activity which may conflict with their independence or integrity.</p>	
25(5)	<p>User inspectorates must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence and must be free from pressures and inducements which might influence their judgement.</p>	Schedule 5 para 6
25(6)	<p><u>Obligation 1:</u> A user inspectorate must be capable of carrying out the conformity assessment tasks assigned to it and in relation to which it has been notified.</p> <p><u>Obligation 2:</u> A user inspectorate must have at its disposal: (a) personnel with technical knowledge and sufficient experience; (b) the descriptions of procedures in accordance with which conformity assessment is carried out; (c) the procedure for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, the degree of complexity of the product technology etc.</p> <p><u>Obligation 3:</u> A user inspectorate must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner.</p>	<p><u>Obligation 1:</u> Schedule 5 para 7</p> <p><u>Obligation 2:</u> Schedule 5 para 8</p> <p><u>Obligation 3:</u> Schedule 5 para 9</p>
25(7)	<p>The personnel responsible for carrying out conformity assessment tasks must have:</p> <p>(a) sound technical and vocational training covering all the relevant conformity assessment activities; (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority; (c) appropriate knowledge and understanding of the essential safety requirements, the relevant harmonised standards and legislation; (d) the ability to draw up certificates, records and reports.</p>	Schedule 5 para 10
25(8)	<p><u>Obligation 1:</u> The impartiality of the user inspectorates, their top level management and the personnel responsible for carrying out conformity assessment tasks must be guaranteed.</p> <p><u>Obligation 2:</u> The remuneration of the top level management and personnel responsible for carrying out conformity assessment tasks must not depend on the number of assessments carried out or on the results</p>	<p><u>Obligation 1:</u> Schedule 5 para 11</p> <p><u>Obligation 2:</u> Schedule 5 para 12</p>

	of the assessments.	
25(9)	User inspectorates must take out liability insurance unless liability is assumed by the Group of which it is part	Schedule 5 para 13
25(10)	<u>Obligation 1:</u> The personnel of a user inspectorate must observe professional secrecy, except in relation to the competent authorities of the Member State in which it is carrying out its activities. <u>Obligation 2:</u> Proprietary rights must be protected.	Schedule 5 para 14, 15
25(11)	User inspectorates must participate in, or ensure that their personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group and must apply as general guidance the administrative decisions and documents produced by that group.	Schedule 5 para 16
26	Where a conformity assessment body demonstrates its conformity with the criteria laid down in relevant harmonised standards, it is to be presumed to comply with the requirements set out in Article 24 or 25 in so far as the applicable harmonised standards cover those requirements.	Regulation 54 This has been elaborated to clarify that the presumption is rebuttable.
27(1)	Where a notified body, user inspectorate or recognised third party organisation subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it must ensure that the subcontractor or the subsidiary meets the requirements set out in Article 25 and must inform the notifying authority accordingly.	Regulation 65(1), (2)
27(2)	Notified bodies, UIs and RTPOs must take full responsibility for the tasks performed by subcontractor or subsidiary	Regulation 65(5)
27(3)	Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.	Regulation 65(3)
27(4)	Notified bodies, UIs and RTPOs must keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them.	Regulation 65(4)
28(1)	A conformity assessment body must submit an application for notification to the notifying authority of the Member State in which it is established.	Regulation 56(2), 57(2) and 58(2)
28(2)	The application must be accompanied by a description of the conformity assessment activities, the conformity assessment module for which the body claims to be competent, as well as by any accreditation certificate issued by a national accreditation body.	Regulation 56(2)(a) and (b), 57(2)(a) and (b), 58(2)(a) and (b)
28(3)	Where the conformity assessment body cannot provide an accreditation certificate, it must provide the notifying authority with all the documentary evidence	Regulation 56(2)(c), 57(2)(c), 58(2)(c)

	necessary for the verification, recognition and regular monitoring of its compliance with the requirements in Article 24 or 25.	
29(1)	Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements in Article 24 or 25.	Regulation 55(1)
29(2)	They must notify the Commission and other Member States using the electronic notification tool developed and managed by the Commission.	Unnecessary to implement explicitly.
29(3)	The notification must include full details of the conformity assessment activities, the conformity assessment module and pressure equipment concerned and the relevant attestation of competence.	Regulation 59
29(4)	Where a notification is not based on an accreditation certificate, the notifying authority must provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that the body is monitored regularly and will continue to satisfy the requirements laid down in Article 24 or 25.	Regulation 59(c)
29(5)	The body concerned may perform the activities of a notified body, RTPO or UI only where no objections are raised by the Commission or other Member States within 2 weeks, where an accreditation certificate is used, or 2 months otherwise. Only such a body is to be considered a notified body, RTPO or UI for the purposes of this Directive.	Regulation 51(1)(b), 52(1)(b), 53(1)(b)
29(6)	The notifying authority must notify the Commission and other Member States of any subsequent relevant changes to the notification.	Regulation 62(5)
30(1)	<u>Obligation 1:</u> The Commission must assign an identification number to a notified body. <u>Obligation 2:</u> It must assign a single such number even where the body is notified under several Union acts.	It is not necessary to implement these obligations because these are obligations on the European Commission.
30(2)	<u>Obligation 1:</u> The Commission must make publicly available the list of notified bodies. <u>Obligation 2:</u> The Commission must ensure that the list is kept up to date.	It is not necessary to implement these obligations because these are obligations on the European Commission.
31	<u>Obligation 1:</u> The Commission must make publicly available the list of recognised third party organisations and user inspectorates. <u>Obligation 2:</u> The Commission must ensure that the list is kept up to date.	It is not necessary to implement these obligations because these are obligations on the European Commission.
32	<u>Obligation 1:</u> Where a notifying authority has ascertained or has been informed that a notified body or recognised third party organisation no longer meets	<u>Obligation 1:</u> Regulation 62(1, (3) and (4)

	<p>the requirements laid down in Article 24 or that it is failing to fulfil its obligations, the notifying authority must restrict, suspend or withdraw notification, depending on the seriousness of the failure.</p> <p><u>Obligation 2:</u> The notifying authority must immediately inform the Commission and the other Member States.</p>	<p><u>Obligation 2:</u> Regulation 62(5)</p>
32(2)	<p>In the event of a restriction, suspension or withdrawal of notification, or where the notified body, recognised third party organisation or user inspectorate has ceased activity, the notifying Member State must take appropriate steps to ensure that the files are either processed by another body or kept available for the responsible notifying and market surveillance authorities.</p>	<p>Regulation 62(6)</p>
33(1)	<p>The Commission must investigate any doubts regarding the competence of a body or whether the body is fulfilling its responsibilities.</p>	<p>It is not necessary to implement this obligation because it is an obligation on the European Commission.</p>
33(2)	<p>The notifying Member State must provide the Commission, on request, with information relating to the basis for the notification or the maintenance of the competence of the body concerned.</p>	<p>It is not necessary to implement this obligation explicitly.</p>
33(3)	<p>The Commission must ensure that all sensitive information obtained in the course of its investigations is treated confidentially.</p>	<p>It is not necessary to implement this obligation because it is an obligation on the European Commission.</p>
33(4)	<p>Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for notification, it must adopt an implementing act requesting the notifying Member State to take the necessary corrective action.</p>	<p>It is not necessary to implement this obligation because it is an obligation on the European Commission.</p>
34(1)	<p>Notified bodies, recognised third party organisations and user inspectorates must carry out conformity assessments in accordance with the conformity assessment procedures set out in Annex I.</p>	<p>Regulation 64 and Schedule 6</p>
34(2)	<p>Conformity assessment activities shall be carried out in a proportionate manner, taking account of all listed factors but respecting the level of protection required.</p>	<p>Regulation 64 and Schedule 6, para 2, 3, 4</p>
34(3)	<p>Where a notified body finds that essential safety requirements set out in Annex 1 or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it must require the manufacturer to take appropriate corrective measures and must not issue a certificate of conformity.</p>	<p>Schedule 6, paragraph 5</p>
34(4)	<p>Where, in the course of monitoring of conformity</p>	<p>Schedule 6, paragraph 6</p>

	following the issue of a certificate, a notified body finds that a vessel no longer complies, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate, if necessary.	
34(5)	Where corrective measures are not taken or do not have the required effect, the notified body must restrict, suspend or withdraw any certificates.	Schedule 6, paragraph 7
35	Member States must ensure that an appeal procedure against decisions of the notified body is available.	Schedule 4, paragraph 11
36(1)	Notified bodies, recognised third party organisations and user inspectorates must inform the notifying authority of: (a) any refusal, restriction, suspension or withdrawal of a certificate; (b) any circumstances affecting the scope or conditions for notification; (c) any request for information received from market surveillance authorities; and (d) on request, conformity assessment activities performed etc.	Schedule 6 paragraph 10
36(2)	Notified bodies must provide other bodies notified under the Directive carrying out similar conformity assessment activities covering the same pressure equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.	Schedule 6 paragraph 12
37	The Commission must provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
38	<u>Obligation 1:</u> The Commission must ensure that appropriate coordination and cooperation between notified bodies are put in place. <u>Obligation 2:</u> Member States must ensure that the bodies notified by them participate in the forum.	<u>Obligation 1:</u> - It is not necessary to implement this obligation because it is an obligation on the European Commission. <u>Obligation 2:</u> Schedule 6, paragraph 13
39	Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 apply to pressure equipment and assemblies covered by the Directive.	Part 5 and Schedules 7, 8 and 9 Regulation (EC) 765/2008 is directly applicable in United Kingdom law. Part 5 of these Regulations provides for enforcing authorities to use their powers to give effect to

		Regulation (EC) 765/2008.
40(1)	<p><u>Obligation 1:</u> Where a market surveillance authority has reason to believe that pressure equipment or assemblies present a risk to health or safety of persons or to domestic animals or property, it must carry out an evaluation in relation to the equipment or assembly concerned.</p> <p><u>Obligation 2:</u> The relevant economic operators must cooperate as necessary with the market surveillance authorities for the purposes of the evaluation.</p> <p><u>Obligation 3:</u> Where, in the course of an evaluation, the market surveillance authority finds that the equipment or assembly does not comply, it must require the economic operator to take all appropriate corrective action within a reasonable period.</p> <p><u>Obligation 4:</u> The market surveillance authority must inform the relevant notified body accordingly.</p> <p><u>Obligation 5:</u> Article 21 of Regulation (EC) No 765/2008 applies to the corrective action required.</p>	<p><u>Obligation 1:</u> Regulation 70(1)</p> <p><u>Obligation 2:</u> Regulations 18(4)(a) and 29(4)(a)</p> <p><u>Obligation 3:</u> Regulation 71(1) and (9)</p> <p><u>Obligation 4:</u> Regulation 71(2)</p> <p><u>Obligation 5:</u> Regulation 75</p>
40(2)	Where the market surveillance authority considers that non-compliance is not restricted to their national territory, they must inform the Commission and other Member States of the result of the evaluation and the actions that it has required of the economic operator.	Regulation 71(4)
40(3)	The economic operator must ensure that all appropriate corrective action is taken in respect of all the pressure equipment and assemblies concerned that it has made available on the market.	Regulations 18(4) and 29(4)
40(4)	<p><u>Obligation 1:</u> Where the relevant economic operator does not taken adequate corrective action, the market surveillance authority must take appropriate measures to prohibit or restrict the equipment or assembly being made available on the national market, to withdraw the equipment or assembly from the market or to recall it.</p> <p><u>Obligation 2:</u> The market surveillance authority must inform the Commission and the other Member States of those measures.</p>	<p><u>Obligation 1:</u> Regulation 71(5)</p> <p><u>Obligation 2:</u> Regulation 71(7)</p>
40(5)	<u>Obligation 1:</u> The information provided to the Commission and other Member States must include certain information, including data necessary for the identification of the equipment or assembly, the nature of the non-compliance and the risk, the nature of the national measures taken etc.	<p><u>Obligation 1:</u> Regulation 71(8)</p> <p><u>Obligation 2:</u> Regulation 71(8)(f)</p>

	<u>Obligation 2</u> : The information provided must indicate whether the non-compliance is due to either failure to meet requirements under the Directive or shortcomings in the harmonised standards.	
40(6)	Member States other than the one initiating the procedure must inform the Commission and other Member States of any measures adopted and any information at their disposal relating to the non-compliance of the equipment or assembly, and any objections to the adopted national measure.	Regulation 72(2)
40(7)	If no objections are raised within 3 months of receipt of the information, the measure is considered justified.	It is not necessary to implement this provision. It concerns a procedure that takes place at the EU level.
40(8)	Member States must ensure that appropriate restrictive measures are taken in respect of a vessel without delay.	Regulation 72(3)
41(1)	Where, on completion of the procedure in Article 40 of the Directive, objections are raised, the Commission must enter into consultation, evaluate the national measure, adopt an implementing act determining whether the national measure is justified and communicate its decision to Member States and relevant economic operators.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
41(2)	<u>Obligation 1</u> : If the national measure is considered justified, all Member States must take the necessary measures to ensure that the non-compliant equipment or assembly is withdrawn from their national market and inform the Commission accordingly. <u>Obligation 2</u> : If the national measure is considered unjustified, the Member State concerned must withdraw that measure.	<u>Obligation 1</u> : Regulation 72(4) and (6) <u>Obligation 2</u> : Regulation 72(7)
41(3)	Where the national measure is considered justified and the non-compliance is attributed to a shortcoming in the harmonised standards, the Commission must apply the procedure provided for in Regulation (EU) No 1025/2012.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
42(1)	Where, having carried out an evaluation, a Member State finds that although pressure equipment or an assembly is in compliance with the Directive, it presents a risk to the health or safety of persons, to domestic animals or property, it must require the relevant economic operator to take all appropriate measures to ensure that the equipment or assembly, when placed on the market, no longer presents the risk, to withdraw it or to recall it within a reasonable period.	Regulation 73(1) and (5)
42(2)	The economic operator must ensure that corrective action is taken in respect of all the equipment or	Regulations 18(4)(b) and 29(4)(b)

	assemblies concerned that he has made available on the market throughout the Union.	This obligation does not require further implementation as it is already reflected in the obligation to cooperate.
42(3)	The Member State must inform the Commission and other Member States and provide the data necessary to identify the equipment or assembly, the origin and the supply chain, the nature of the risk and the nature of the national measures taken.	Regulation 73(3) and (4)
42(4)	The Commission must enter into consultation, evaluate the national measures and decide whether the national measure is justified.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
42(5)	The Commission must address its decision to all Member States and the relevant economic operators.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
43(1)	Where a Member State makes a finding of formal non-compliance, it must require the relevant economic operator to put an end to the non-compliance concerned.	Regulation 74(1)
43(2)	Where the non-compliance persists, the Member State must take appropriate measures to restrict or prohibit the equipment or assembly being made available on the market or ensure that it is recalled or withdrawn from the market.	Regulation 74(3)
44(1)	The Commission is to be assisted by the Committee on Pressure Equipment.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
44(2)	Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 applies.	It is not necessary to implement this provision as it concerns a process at the EU level.
44(3)	Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 applies.	It is not necessary to implement this provision as it concerns a process at the EU level.
44(4)	Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011 applies.	It is not necessary to implement this provision as it concerns a process at the EU level.
44(5)	Consultation of the Committee	It is not necessary to implement this provision as it concerns a process at the EU level.

45(1)	The Commission may adopt delegated acts to take into account serious safety reasons	It is not necessary to implement this obligation because it is a process for the European Commission.
45(2)	A Member State having concerns about the safety of pressure equipment or assemblies must inform the Commission	Regulation 71(7)
45(3)	Prior to adopting a delegated act the Commission must carry out an assessment	It is not necessary to implement this obligation because it is an obligation on the European Commission.
46	Exercise of the delegation	It is not necessary to implement this obligation because it concerns a process at the EU level.
47	Member States must lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and must take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided must be effective, proportionate and dissuasive.	Part 5 (and in particular, regulations 76 and 77)
48(1)	Member State must not impede the putting into service of equipment or assemblies which comply with the regulations in force at the date of application of Directive 97/23/EC and were placed on the market before 29 May 2002.	Regulation 88(2)
48(2)	Member State must not impede the making available on the market and/or putting into service of equipment or assemblies which are in conformity with Directive 97/23/EC and which were placed on the market before 19 July 2016.	Regulation 88(1)
48(3)	Certificates and decisions issued by conformity assessment bodies under Directive 97/23/EC shall be valid under this Directive	Regulation 89
49(1)	Member States must adopt and publish their measures implementing Article 13 by 28 February 2016 and must apply them from 1 June 2015. Where Member States adopt the measures, they must contain a reference to this Directive. They must also include a statement that references in existing laws to the Directive repealed are to be construed as references	It is not necessary to implement this obligation explicitly. This obligation was satisfied by the adoption of the Pressure Equipment (Amendment)

	to the new Directive.	Regulations 2015 (SI 2015/399).
49(2)	Member States must adopt and publish their remaining implementing measures by 18 July 2016 and apply those measures from 19 July 2016. Where Member States adopt the measures, they must contain a reference to this Directive. They must also include a statement that references in existing laws to the Directive repealed are to be construed as references to the new Directive.	It is not necessary to implement this obligation explicitly.
49(3)	Member States must communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	It is not necessary to implement this obligation explicitly.
50	Article 9 of Directive 97/23/EC is repealed from 1 June 2015 and other provisions of Directive 97/23/EC are repealed from 129 July 2016. References to the repealed Directive are to be construed as reference to the new Directive.	It is not necessary to implement this obligation as it operates at the EU level.
51	The Directive enters into force on the twentieth day following its publication and certain articles apply from 19 July 2016	It is not necessary to implement this obligation as it operates at the EU level.
52	This Directive is addressed to Member States.	It is not necessary to implement this provision.
Annex I	Essential safety requirements	Schedule 2 to the Regulations
Annex II	Conformity assessment tables	Incorporated by reference to the Directive
Annex III	Conformity assessment procedures	Incorporated by reference to the Directive
Annex IV	EU declaration of conformity	Schedule 11
Annex V	Repeals and time limits for transposition referred to Article 43	It is not necessary to implement these provisions.
Annex VI	Correlation table	It is not necessary to implement these provisions.