SUBSIDIARY LEGISLATION 427.01

SIMPLE PRESSURE VESSELS REGULATIONS

20th April, 2016*

LEGAL NOTICE 99 of 2016, as amended by Legal Notice 257 of 2026.

Citation and scope.

1. (1) The title of these regulations is the Simple Pressure Vessels Regulations.

(2) These regulations transpose Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (recast).

Making available on the market of safety components for vessels covered by the Simple Pressure Vessels Order, 1998.

2. (1) The putting into service of vessels or the making available on the market of safety components for vessels covered by the Simple Pressure Vessels Order, 1998 which are in conformity with those regulations and which were placed on the market before 20th April 2016 shall not be impeded.

(2) Certificates and decisions by notified bodies issued under Simple Pressure Vessels Order, 1998 shall be valid under these regulations.

Applicability.

3. (1) These regulations shall apply to simple pressure vessels ('vessels') manufactured in series with the following characteristics:

(*a*) the vessels are welded, intended to be subjected to an internal gauge pressure greater than 0.5 bar and to contain air or nitrogen, and are not intended to be fired;

(*b*) the parts and assemblies contributing to the strength of the vessel under pressure are made either of non-alloy quality steel or of non-alloy aluminium or non-age hardening aluminium alloys;

(*c*) the vessel is made of either of the following elements:

(i) a cylindrical part of circular cross-section closed by outwardly dished and/or flat ends which revolve around the same axis as the cylindrical part;

(ii) two dished ends revolving around the same axis;

(*d*) the maximum working pressure of the vessel does not exceed 30 bar and the product of that pressure and the capacity of the vessel (PS × V) does not exceed 10 000 bar.L;

(*e*) the minimum working temperature is no lower than -50°C and the maximum working temperature is not higher than 300°C for steel and 100°C for aluminium or aluminium alloy vessels.

(2) These regulations shall not apply to:

* See regulation 2(1) of these Regulations as originally promulgated.

(*a*) vessels specifically designed for nuclear use, failure of which may cause an emission of radioactivity;

(*b*) vessels specifically intended for installation in or the propulsion of ships and aircraft;

(*c*) fire extinguishers.

Definitions.
Amended by:
L.N. 257 of 2026.

4. For the purposes of these regulations, the following definitions shall apply:

"accreditation" means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

"authorised representative" means any natural or legal person established within the Union 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 vessel is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

"common specifications" means a set of technical requirements established to ensure compliance with regulatory obligations when harmonised standards are unavailable or insufficient;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

"conformity assessment" means the process demonstrating whether the essential safety requirements of these regulations relating to a vessel have been fulfilled;

"crisis-relevant goods" means goods that are non-substitutable, non-diversifiable or indispensable in the maintenance of vital societal functions or economic activities in order to ensure the proper functioning of the internal market and its supply chains and that are considered essential for responding to a crisis during the internal market emergency mode that may be activated pursuant to Article 18(4) of Regulation (EU) 2024/2747 with respect to vessels covered by these regulations;

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

"economic operators" means the manufacturer, the authorised representative, the importer and the distributor;

"harmonised standard" means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

"implementing act" means a non-legislative act adopted by the European Commission for the purpose of providing rules and measures necessary for the implementation of these regulations and which are essential to provide for crisis situations during an internal market emergency mode activated pursuant to Article 18(4) of Regulation (EU) 2024/2747 with respect to vessels covered by these regulations;

"importer" means any natural or legal person established within the Union who places a vessel from a third country on the Union market;

"internal market emergency mode" means internal market emergency mode as defined in sub-article (3) of Article 3 of Regulation (EU) 2024/2747;

"making available on the market" means any supply of a vessel for distribution or use on the Union market 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 vessel or has a vessel designed or manufactured, and markets that vessel under his name or trade mark;

"national accreditation body" means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

"notified body" means a conformity assessment body which has been officially designated by its national authority and notified to the Commission to carry out the procedures for conformity assessment of certain products in accordance with regulation 15 before being placed on the market;

"placing on the market" means the first making available of a vessel on the Union market;

"recall" means any measure aimed at achieving the return of a vessel that has already been made available to the end- user;

"Regulation (EU) 2024/2747" means Regulation (EU) 2024/2747 of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act);

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

"Technical Regulations Division" or "TRD" means the Technical Regulations Division established under Part VI of the Malta Competition and Consumer Affairs Authority Act; Cap. 510.

"Union harmonisation legislation" means any Union legislation harmonising the conditions for the marketing of vessels;

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

Making available on the market and putting into service.

5. (1) Vessels may be made available on the market or put into service only if they satisfy the requirements of these regulations when they are properly installed and maintained and used for the purposes for which they are intended.

(2) The provisions of these regulations shall not affect the right from laying down any the requirements deemed necessary to ensure that workers are protected when using vessels, provided that this does not mean that those vessels are modified in a way unspecified in these regulations.

Essential requirements.

6. (1) Vessels of which the product of PS × V exceeds 50 bar.L shall satisfy the essential safety requirements set out in Schedule I.

(2) Vessels of which the product of PS × V is 50 bar.L or less shall be designed and manufactured in accordance with the sound engineering practice in one of the Member States.

Free movement.

7. The making available on the market and the putting into service of vessels which satisfy the requirements of these regulations shall not be impeded.

Obligations of the manufacturer.

8. (1) When placing on the market their vessels of which the product of PS × V exceeds 50 bar.L, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Schedule I.

(2) When placing on the market their vessels of which the product of PS × V is 50 bar.L or less, manufacturers shall ensure that they have been designed and manufactured in accordance with the sound engineering practice in one of the Member States.

(3) For vessels of which the product of PS × V exceeds 50 bar.L, manufacturers shall draw up the technical documentation referred to in Schedule II and carry out the relevant conformity assessment procedure referred to in regulation 15 or have it carried out.

(4) Where compliance of a vessel of which the product of PS × V exceeds 50 bar.L with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the inscriptions provided for in point 1 of Schedule III.

(5) Manufacturers shall ensure that vessels of which the product of PS × V is 50 bar.L or less, bear the inscriptions laid down in point 1 of Schedule III.

(6) Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the vessel has been placed on the market.

(7) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with these regulations. Changes in vessels design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a vessel is declared shall be adequately taken into account.

(8) When deemed appropriate with regard to the risks presented by a vessel, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of vessels made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming vessels and vessel recalls, and shall keep distributors informed of any such monitoring.

(9) Manufacturers shall ensure that vessels which they have placed on the market bear a type and serial or batch identification allowing their identification.

(10) Manufacturers shall indicate on the vessel their name, registered trade name or registered trade mark and the postal address at which they can be contacted. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in at least the Maltese or English language.

(11) Manufacturers shall ensure that the vessel is accompanied by the instructions and safety information referred to in point 2 of Schedule III, in at least the Maltese and English. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

(12) Manufacturers who consider or have reason to believe that a vessel which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that vessel into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the vessel presents a risk, manufacturers shall immediately inform the Technical Regulations Division to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(13) Manufacturers shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the vessel with these regulations, in at least the Maltese or English language. They shall cooperate with the Technical Regulations Divisions, at its request, on any action taken to eliminate the risks posed by vessels which they have placed on the market.

Authorised representatives.

9. (1) A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in regulation 8(1) and the obligation to draw up technical documentation referred to sub-regulation (3) shall not form part of the authorised representative's mandate.

(2) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(*a*) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the vessel has been placed on the market;

(*b*) further to a reasoned request from the Technical Regulations Divisions, provide that authority with all the information and documentation necessary to demonstrate the conformity of a vessel;

(*c*) cooperate with the Technical Regulations Divisions, at their request, on any action taken to eliminate the risks posed by vessels covered by the authorised representative's mandate.

Obligations of importers.

10. (1) Importers shall place only compliant vessels on the market.

(2) Before placing on the market a vessel of which the product of PS × V exceeds 50 bar.L, importers shall ensure that the appropriate conformity assessment procedure referred to in regulation 15 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the vessel bears the CE marking and the inscriptions provided for in point 1 of Schedule III and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in regulation 8(9) and regulation 8(10).

(3) Where an importer considers or has reason to believe that a vessel of which the product of PS × V exceeds 50 bar.L is not in conformity with the essential safety requirements set out in Schedule I, he shall not place the vessel on the market until it has been brought into conformity. Furthermore, where the vessel presents a risk, the importer shall inform the manufacturer and the Technical Regulations Division to that effect.

(4) Before placing on the market a vessel of which the product of PS × V is 50 bar.L or less, importers shall ensure that it has been designed and manufactured in accordance with the sound engineering practice in one of the Member States, bears the inscriptions provided for in point 1.2 of Schedule III and that the manufacturer has complied with the requirements set out in regulation 8(9) and regulation 8(10).

(5) Importers shall indicate on the vessel their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the vessel. The contact details shall be in at least the Maltese or English language.

(6) Importers shall ensure that the vessel is accompanied by the instructions and safety information referred to in point 2 of Schedule III, in at least the Maltese or English language.

(7) Importers shall ensure that, while a vessel in respect of which the product of PS × V exceeds 50 bar.L is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Schedule I.

(8) When deemed appropriate with regard to the risks presented by a vessel, importers shall, to protect the health and safety of end-users, carry out sample testing of vessels made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming vessels and vessel recalls, and shall keep distributors informed of any such monitoring.

(9) Importers who consider or have reason to believe that a vessel which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that vessel into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the vessel presents a risk, importers shall immediately inform the

Technical Regulations Division to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(10) For vessels of which the product of PS × V exceeds 50 bar.L, importers shall, for 10 years after the vessel has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the Technical Regulations Division and ensure that the technical documentation can be made available to that authority, upon request.

(11) Importers shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a vessel in at least the Maltese or English language. They shall cooperate with the Technical Regulations Divisions, at its request, on any action taken to eliminate the risks posed by vessels which they have placed on the market.

Obligations of distributors.

11. (1) When making a vessel available on the market distributors shall act with due care in relation to the requirements of these regulations.

(2) Before making available on the market a vessel of which the product of PS × V exceeds 50 bar.L, distributors shall verify that the vessel bears the CE marking and the inscriptions provided for in point 1 of Schedule III, that it is accompanied by the required documents and by instructions and safety information referred to in point 2 of Schedule III in at least the Maltese or English language, and that the manufacturer and the importer have complied with the requirements set out in regulations 8(9) and 8(10) and regulation 10(5) respectively.

(3) Where a distributor considers or has reason to believe that a vessel of which the product of PS × V exceeds 50 bar.L is not in conformity with the essential safety requirements set out in Schedule I, he shall not make the vessel available on the market until it has been brought into conformity. Furthermore, where the vessel presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

(4) Before making available on the market a vessel of which the product of PS × V is 50 bar.L or less, distributors shall verify that the vessel bears the inscriptions provided for in point 1.2 of Schedule III and is accompanied by the instructions and safety information referred to in point 2 of Schedule III in at least the Maltese or English language, and that the manufacturer and the importer have complied with the requirements set out in regulation 8(9) and regulation 8(10) and regulation 10(5) respectively.

(5) Distributors shall ensure that, while a vessel of which the product of PS × V exceeds 50 bar.L is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Schedule I.

(6) Distributors who consider or have reason to believe that a

vessel which they have made available on the market is not in conformity with these regulations shall make sure that the corrective measures necessary to bring that vessel into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the vessel presents a risk, distributors shall immediately inform the Technical Regulations Division to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(7) Distributors shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a vessel. They shall cooperate with the Technical Regulations Divisions, at its request, on any action taken to eliminate the risks posed by vessels which they have made available on the market.

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

12. An importer or distributor shall be considered a manufacturer for the purposes of these regulations and he shall be subject to the obligations of the manufacturer under regulation 8, where he places a vessel on the market under his name or trade mark or modifies a vessel already placed on the market in such a way that compliance with these regulations may be affected.

Identification of economic operators.

13. (1) Economic operators shall, on request, identify the following to the market surveillance authorities:

(*a*) any economic operator who has supplied them with a vessel;

(*b*) any economic operator to whom they have supplied a vessel.

(2) Economic operators shall be able to present the information referred to in sub-regulation (1) for 10 years after they have been supplied with the vessel and for 10 years after they have supplied the vessel.

Presumption of conformity of vessels of which the product of PS × V exceeds 50 bar.L

14. Vessels of which the product of PS × V exceeds 50 bar.L and which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential safety requirements set out in Schedule I covered by those standards or parts thereof.

Conformity assessment procedures.

15. (1) Prior to their manufacture, vessels of which the product of PS × V exceeds 50 bar.L shall be subject to the EU-type examination (Module B) set out to in point 1 of Schedule II, as follows:

(*a*) for vessels manufactured in accordance with the harmonised standards referred to in regulation 14, at the choice of the manufacturer, in either of the following two manners:

(i) assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence without examination of a specimen

(Module B - design type);

(ii) assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence, plus examination of a prototype, representative of the production envisaged, of the complete vessel (Module B – production type).

(*b*) for vessels not manufactured, or manufactured only partly, in accordance with the harmonised standards referred to in regulation 14, the manufacturer shall submit for examination a prototype, representative of the production envisaged, of the complete vessel and the technical documentation and supporting evidence for examination and assessment of the adequacy of the technical design of the vessel (Module B - production type).

(2) Prior to their placing on the market, vessels shall be subject to the following procedures:

(*a*) where the product of PS × V exceeds 3 000 bar.L, to conformity to type based on internal production control plus supervised vessel testing (Module C1) set out in point 2 of Schedule II;

(*b*) where the product of PS × V does not exceed 3 000 bar.L but exceeds 200 bar.L, at the choice of the manufacturer, to either of the following:

(i) conformity to type based on internal production control plus supervised vessel testing (Module C1) set out in point 2 of Schedule II;

(ii) conformity to type based on internal production control plus supervised vessel checks at random intervals (Module C2) set out in point 3 Schedule II;

(*c*) where the product of PS × V does not exceed 200 bar.L but exceeds 50 bar.L, at the choice of the manufacturer, to either of the following:

(i) conformity to type based on internal production control plus supervised vessel testing (Module C1) set out in point 2 of Schedule II;

(ii) conformity to type based on internal production control (Module C) set out in point 4 of Schedule II.

(3) The records and correspondence relating to the conformity assessment procedures referred to in sub-regulations (1) and (2) shall be drawn up in at least the Maltese and English language.

EU Declaration of Conformity.

16. (1) The EU declaration of conformity shall state that the fulfilment of the essential safety requirements set out in Schedule I has been demonstrated.

(2) The EU declaration of conformity shall have the model

structure set out in Schedule IV, shall contain the elements specified in the relevant modules set out in Schedule II and shall be continuously updated. It shall be translated into either the Maltese or English language.

(3) Where a vessel is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

(4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the vessel with the requirements laid down in these regulations.

CE marking.

17. (1) The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

(2) The CE marking and the inscriptions referred to in point 1 of Schedule III shall be affixed visibly, legibly and indelibly to the vessel or to its data plate.

(3) The CE marking shall be affixed before the vessel is placed on the market.

(4) The CE marking shall be followed by the identification number of the notified body involved in the production control phase. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

(5) The CE marking and the identification number of the notified body may be followed by any other mark indicating a special risk or use.

(6) The Technical Regulations Division shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Notification of conformity assessment bodies.

18. (1) The Technical Regulations Division shall notify the European Commission and the other Member States of bodies authorised to carry out third-party conformity assessment under these regulations.

(2) The Technical Regulations Division shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with regulations 19(13) to 19(16).

(3) The assessment and monitoring referred to in sub-regulation (2) shall be carried out by the National Accreditation Board (Malta).

(4) The Technical Regulations Division shall take full responsibility for the tasks performed by National Accreditation Board (Malta) referred to in sub-regulation (3).

(5) The Technical Regulations Division shall inform the

European Commission of its procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

Requirements relating to notified bodies.

S.L. 427.45

19. (1) For the purposes of notification under these regulations, a conformity assessment body shall meet the requirements laid down in sub-regulations (2) to (11) and in the Method for Designating Conformity Assessment Bodies Regulations.

(2) A conformity assessment body shall be established under Maltese law and have legal personality.

(3) A conformity assessment body shall be a third-party body independent of the organisation or vessel it assesses. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of vessels which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

(4) (*a*) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of vessels which they assess, nor representative of any of those parties. This shall not preclude the use of assessed vessels that are necessary for the operations of the conformity assessment body or the use of such vessels personal purposes. This does not preclude the possibility of exchange of technical information between the manufacturer or the installer and the body.

(*b*) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those vessels or safety components for vessels, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

(*c*) Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

(5) Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence

their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

(6) (*a*) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Schedule IV to XII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

(*b*) At all times and for each conformity assessment procedure and each kind of vessel in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(i) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(ii) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(iii) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

(*c*) A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

(7) The personnel responsible for carrying out conformity assessment tasks shall have the following:

(*a*) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(*b*) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(*c*) appropriate knowledge and understanding of the essential safety requirements set out in Schedule I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;

(*d*) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

(8) The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed. The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

(9) Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

(10) The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under point 3.2 of Schedule I and under Schedule II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

(11) Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

(12) Where a conformity assessment body 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 of the European Union* it shall be presumed to comply with the requirements set out in sub-regulations (1) to (11) insofar as the applicable harmonised standards cover those requirements.

(13) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in sub-regulations (1) to (11) and shall inform the Technical Regulations Division accordingly.

(14) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

(15) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(16) Notified bodies shall 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 under point 3.2 of Schedule I and under Schedule II.

Notification procedures.

20. (1) A conformity assessment body established in Malta shall submit an application for notification under these regulations

to the Technical Regulations Division.

(2) The application referred to in the preceding sub-regulation shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the vessel or vessels for which that body claims to be competent, as well as by an accreditation certificate, issued by the National Accreditation Board (Malta) attesting that the conformity assessment body fulfils the requirements laid down in regulations 19(1) to 19(11) and the Method for Designating Conformity Assessment Bodies Regulations.

S.L. 427.45

(3) The Technical Regulations Division may only notify conformity assessment bodies which have satisfied the requirements laid down in regulation 21 and the Method for Designating Conformity Assessment Bodies Regulations.

S.L. 427.45

(4) The Technical Regulations Division shall notify conformity assessment bodies to the European Commission and the other Member States using the electronic notification tool developed and managed by the European Commission.

(5) The notification shall include full details of the conformity assessment activities, the conformity assessment procedure or procedures and the vessels or the safety component for vessels concerned and the relevant attestation of competence.

(6) The body concerned may perform the activities of a notified body only where no objections are raised by the European Commission or the other Member States within two weeks of a notification. Only such a body shall be considered a notified body for the purposes of these regulations.

(7) The Technical Regulations Division shall notify the European Commission and the other Member States of any subsequent relevant changes to the notification.

(8) Where the Technical Regulations Division has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulations 19(1) to 19(11) or the Method for Designating Conformity Assessment Bodies Regulations, or that it is failing to fulfil its obligations, the Technical Regulations Division shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the European Commission and the other Member States accordingly.

S.L. 427.45

(9) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the Technical Regulations Division shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the responsible notifying and Technical Regulations Division, at their request.

(10) The Technical Regulations Division shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

Operational obligations of notified bodies.

21. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Schedule II.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall 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 technology of the vessel in question and the mass or serial nature of the production process. In so doing, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the vessel with these regulations.

(3) Where a notified body finds that the essential safety requirements set out in Schedule I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

(4) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a vessel no longer complies; it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

(5) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

(6) Notified bodies shall inform the Technical Regulations Division of the following:

(*a*) any refusal, restriction, suspension or withdrawal of a certificate;

(*b*) any circumstances affecting the scope of or conditions for notification;

(*c*) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(*d*) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(7) Notified bodies shall provide the other bodies notified these regulations carrying out similar conformity assessment activities covering the same vessels with relevant information on issues relating to negative and, on request, positive conformity assessment results.

(8) Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the European Commission.

Market surveillance.

22. (1) The Technical Regulations Division shall take appropriate measures to ensure that vessels may only be placed on

the market if they satisfy the essential safety requirements set out in Schedule I.

(2) Article 15(3) and Articles 16 to 29 of regulation (EC) No 765/2008 shall apply to vessels covered by regulation 3 of these regulations.

(3) Where the Technical Regulations Division have sufficient reasons to believe that a vessel covered by these regulations presents a risk to the health or safety of persons or, where appropriate to the safety of property, they shall carry out an evaluation in relation to the vessel concerned covering all relevant requirements laid down in these regulations. The relevant economic operators shall cooperate as necessary with the Technical Regulations Division for that purpose.

(4) Where, in the course of the evaluation referred to in the sub-regulation (3), the Technical Regulations Division find that a vessel does not comply with the requirements laid down in these regulations, they shall without delay require the installer to take all appropriate corrective actions to bring the vessels into compliance with those requirements, to withdraw the vessels from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe. They shall also inform the notified body accordingly.

(5) Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in sub-regulation (4).

(6) Where the Technical Regulations Division consider that non-compliance is not restricted to the Maltese territory, it shall inform the European Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

(7) The economic operator shall ensure that all appropriate corrective action is taken in respect of all the vessels concerned that it has made available on the market throughout the European Union.

(8) Where the relevant economic operator does not take adequate corrective action within the period referred to in sub-regulation (4), the Technical Regulations Division shall take all appropriate provisional measures to prohibit or restrict the vessel's being made available on the Maltese market, to withdraw the vessel from the Maltese market or to recall it.

(9) The Technical Regulations Division shall inform the European Commission and the other Member States, without delay, of those measures.

(10) The information referred to in sub-regulation (9) shall include all available details, in particular the data necessary for the identification of the non-compliant vessel, the origin of the vessel, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, Technical Regulations Division shall indicate whether the non-compliance is due to either of the following:

(*a*) failure of the vessel to meet requirements relating to the health or safety of persons, to the protection of domestic animals or property; or

(*b*) shortcomings in the harmonised standards referred to in regulation 14 conferring a presumption of conformity.

(11) When the procedure under this Regulation is initiated by another Member State, the Technical Regulations Division, shall without delay inform the European Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the vessel concerned, and, in the event of disagreement with the adopted national measure, of their objections.

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

(13) In such cases, the Technical Regulations Division shall ensure that appropriate restrictive measures, such as withdrawal of the vessel from the market, are taken in respect of the vessel concerned without delay.

(14) Where on completion of the procedure set out in sub-regulations (7) and (8), objections are raised against the measures taken by Technical Regulations Division; the European Commission shall conduct an evaluation including appropriate consultations with these entities and the relevant economic operator or operators.

(15) If, on the basis of this evaluation, the national measure is considered justified, the Technical Regulations Division shall take the measures necessary to ensure that the placing on the market or use of the non-compliant vessel is withdrawn from the Maltese market and shall inform the European Commission accordingly. If, on the basis of this evaluation, the national measure is considered unjustified, the national measure shall be withdrawn.

(16) Where, having carried out an evaluation under sub-regulation (3), the Technical Regulations Division, finds that although a vessel is in compliance with these regulations, it presents a risk to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the vessel concerned, when placed on the market, no longer presents that risk, to withdraw the vessel from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

(17) The economic operator shall ensure that corrective action is taken in respect of all the vessels concerned that he has made available on the market throughout the European Union.

(18) The Technical Regulations Division, upon consultation with the Commissioner of Police, shall immediately inform the

European Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the vessel concerned, the origin and the supply chain of the vessel, the nature of the risk involved and the nature and duration of the national measures taken.

(19) Without prejudice to sub-regulations (3) to (13), where the Technical Regulations Division and/or the Commissioner of Police make one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(*a*) the CE marking has been affixed in violation of article 30 of regulation (EC) No 765/2008 or of regulation 19;

(*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 regulation 17 or has not been affixed;

(*d*) the inscriptions referred to in point 1 of Schedule III have not been affixed or have been affixed in violation of regulation 17 or point 1 of Schedule III;

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

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

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

(*h*) the information referred to in regulation 8(10) or regulation 10(5) is absent, false or incomplete;

(*i*) any other administrative requirement provided for in regulation 6 or regulation 8 is not fulfilled.

(20) Where the non-compliance referred to in sub-regulation (19) persists, the Technical Regulations Division shall take all appropriate measures to restrict or prohibit the vessel being made available on the Maltese market or ensure that it is recalled or withdrawn from the Maltese market.

(21) The powers of the Commissioner of Police under this regulation may be exercised by any officer or other entity as he may direct.

Application of emergency procedures. *Added by: L.N. 257 of 2026.*

22A. (1) The TRD shall ensure that measures taken in accordance with regulations 22B to 22E apply only during the activation of the internal market emergency procedures in accordance with Article 28 of Regulation (EU) 2024/2747 and by means of an implementing act pursuant to Article 18(4) of Regulation (EU) 2024/2747 with respect to vessels covered by these regulations. The emergency procedures relevant to Union product legislation may be activated as regards those crisis-relevant goods as defined by these regulations.

(2) The TRD shall ensure that measures taken pursuant to regulations 22B to 22E apply only to vessels which have been designated as crisis-relevant goods pursuant to Article 18(4) of

Regulation (EU) 2024/2747.

(3) The TRD shall ensure that measures taken pursuant to regulations 22B to 22E apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/2747:

Provided that regulation 22C(6) shall apply during the internal market emergency mode and after its expiry or deactivation.

Prioritisation of the conformity assessment of vessels designated as crisis-relevant goods. *Added by: L.N. 257 of 2026.*

22B. (1) The provisions of this regulation shall apply to vessels referred to in regulation 22A(1) and which are subject to the conformity assessment procedures referred to in regulation 15 and which require the mandatory involvement of a notified body.

(2) The notified bodies shall prioritise and take all necessary measures to process all applications for a conformity assessment of vessels referred to in sub-regulation (1), irrespective of whether those applications have been filed before or after the activation of the emergency procedures pursuant to regulation 22A.

(3) The prioritisation of applications for a conformity assessment of vessels pursuant to sub-regulation (2) shall not result in additional disproportionate costs for the manufacturers who have filed those applications.

(4) The notified bodies shall take all reasonable measures to increase their testing capacities for vessels referred to in sub-regulation (1) in respect of which they have been notified.

Derogation from the conformity assessment procedures requiring the mandatory involvement of a notified body. *Added by: L.N. 257 of 2026.*

22C. (1) By way of derogation from regulation 15 the TRD shall authorise, on a duly justified request from an economic operator, the placing on the market within the territory of Malta of specific vessels referred to in regulation 22A(1) for which the conformity assessment procedures referred to in regulation 15 which require the mandatory involvement of a notified body have not been carried out:

Provided that compliance with all the applicable essential safety requirements of these regulations has been demonstrated in accordance with procedures referred to in such authorisation. The TRD shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with this sub-regulation.

(2) The specific vessel subject to the extension of validity of the authorisation referred to in sub-regulation (1) shall bear the information that it is placed on the market as a crisis-relevant good. The information and any labelling shall be clear and intelligible and shall be written in the English or Maltese language.

(3) The authorisation granted by the TRD according to sub-regulation (1) shall be valid only in Malta unless it has been

recognised as valid by a national market surveillance authority in another Member State. The TRD shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

(4) Manufacturers and importers of vessels subject to the authorisation procedure referred to in sub-regulation (1) shall declare on their sole responsibility that the vessels concerned comply with all the applicable essential safety requirements of these regulations and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the TRD.

(5) Any authorisation issued pursuant to sub-regulation (1) shall establish the conditions and requirements under which the vessel may be placed on the market. The authorisations shall provide for at least the following:

(a) a description of the procedures, by means of which the compliance with the applicable essential safety requirements of these regulations was successfully demonstrated;

(b) any specific requirements regarding the traceability of the vessel concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the internal market emergency mode has been activated in accordance with Article 18 of Regulation (EU) 2024/2747;

(d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the vessel concerned; and

(e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the vessel concerned that has been placed on the market.

(6) By way of derogation from regulations 7 and 17, vessels for which an authorisation has been granted in accordance with sub-regulation (1) shall not bear the CE marking and the inscriptions provided for in item 1 of Schedule III and regulation 7 shall not apply.

(7) Where an authorisation pursuant to sub-regulations (1) and (2) is valid, the TRD shall with respect to such vessel, take all corrective and restrictive actions provided for under the Market Surveillance and Compliance Regulations and in accordance with these regulations. The TRD shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

S.L. 427.105.

(8) The use of the authorisation procedure established in

sub-regulations (1) and (3) shall not affect the application of the relevant conformity assessment procedures established in regulation 15.

Presumption of conformity based on standards and common specifications. *Added by: L.N. 257 of 2026.*

22D. (1) Without prejudice to regulation 14, vessels which are in conformity with the harmonised standards or common specifications or parts thereof shall be presumed to be in conformity with the essential safety requirements of these regulations which are covered by those standards, common specifications or parts thereof.

(2) From the day following the expiry or deactivation of the internal market emergency mode, it shall no longer be possible for manufacturers to rely on the presumption of conformity provided by the harmonised standards or the common specifications.

(3) By way of derogation from regulation 22A(3), unless there shall be sufficient reason to believe that the vessels covered by the harmonised standards or common specifications referred to in sub-regulation (1) present a risk to the health or safety of persons, the vessels which are in conformity with those standards or common specifications and which have been placed on the market, shall be deemed to be in conformity with the essential safety requirements of these regulations and after the expiry or deactivation of the internal market emergency mode.

(4) When the TRD considers that a standard or common specification as referred to in sub-regulation (1) does not entirely satisfy the essential safety requirements of these regulations, it shall inform the Commission by submitting a detailed explanation thereof.

Prioritisation of market surveillance activities and mutual assistance among authorities. *Added by: L.N. 257 of 2026.*

22E. The TRD shall provide assistance to other market surveillance authorities during an internal market emergency mode, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support.

Penalties.

23. The penalties applicable for the infringement of any of the provisions of these regulations shall be those provided for in Part IV of the Product Safety Act.

Cap. 427

Saving.

24. (1) Any references to the Simple Pressure Vessels Order, 1998, revoked by these Regulations, shall be construed as references to these regulations.

(2) Any references in existing laws, regulations and administrative provisions to Directive 2007/23/EC shall be construed as references to Directive 2013/29/EU.

Schedule I

ESSENTIAL SAFETY REQUIREMENTS

1. Materials

Materials shall be selected according to the intended use of the vessels and in accordance with points 1.1 to 1.4.

1.1. *Pressurised parts*

The materials used for manufacturing the pressurised parts of the vessels shall be:

(*a*) capable of being welded;

(*b*) ductile and tough, so that a rupture at minimum working temperature does not give rise to either fragmentation or brittle-type fracture;

(*c*) not adversely affected by ageing.

For steel vessels, the materials shall in addition meet the requirements set out in point 1.1.1 and, for aluminium or aluminium alloy vessels, those set out in point 1.1.2.

They shall be accompanied by an inspection slip as defined in point (i) of point 3.1 of Schedule III, drawn up by the producer of the materials.

1.1.1. Steel vessels

Non-alloy quality steels shall meet the following requirements:

(*a*) they shall be non-effervescent and supplied after normalisation treatment, or in an equivalent state;

(*b*) the content per product of carbon shall be less than 0.25% and that of sulphur and phosphorus shall each be less than 0.05%;

(*c*) they shall have the following mechanical properties per product:

(i) the maximum tensile strength Rm,max shall be less than 580 N/mm^2;

(ii) the elongation after fracture shall be:

if test pieces are taken parallel to the direction of rolling:

thickness ≥ 3 mm:	A	≥ 22%,
thickness < 3 mm:	$A_{80\ mm}$	≥ 17%,

if test pieces are taken perpendicular to the direction of rolling:

thickness ≥ 3 mm:	A	≥ 20%,
thickness < 3 mm:	$A_{80\ mm}$	≥ 15%;

(iii) the average bending rupture energy KCV for three longitudinal test pieces at minimum working temperature shall not be less than 35 J/cm^2. Not more than one of the three figures may be less than 35 J/cm^2, with a minimum of 25 J/cm^2. In the case of steels intended to be used in the manufacture of vessels the minimum working temperature of which is lower than -10°C and the wall thickness of which exceeds 5 mm, this property shall be checked.

1.1.2. Aluminium vessels

Non-alloy aluminium shall have an aluminium content of at least 99,5% and the alloys referred to in point (*b*) of point 1(1) shall display adequate resistance to intercrystalline corrosion at maximum working temperature.

Moreover, these materials shall satisfy the following requirements:

(*a*) they shall be supplied in an annealed state;

(*b*) they shall have the following mechanical characteristics per product:

- the maximum tensile strength $R_{m,max}$ shall be no more than 350 N/mm^2,
- the elongation after fracture shall be:
  - $A \geq 16\%$ if the test piece is taken parallel to the direction of rolling,
  - $A \geq 14\%$ if the test piece is taken perpendicular to the direction of rolling.

1.2. *Welding materials*

The welding materials used to manufacture the welds on or of the vessel shall be appropriate to and compatible with the materials to be welded.

1.3. *Accessories contributing to the strength of the vessel*

These accessories (for example bolts and nuts) shall be made of a material specified in point 1.1 or of other kinds of steel, aluminium or an appropriate aluminium alloy compatible with materials used for the manufacture of pressurised parts.

The latter materials shall at minimum working temperature have an appropriate elongation after fracture and bending rupture energy.

1.4. *Non-pressurised parts*

All unpressurised parts of welded vessels shall be of materials which are compatible with that of the components to which they are welded.

2. Vessel design

(*a*) The manufacturer shall, when designing the vessel, define the use to which it will be put, and select:

(i) the minimum working temperature T_{min};

(ii) the maximum working temperature T_{max};

(iii) the maximum working pressure PS.

However, should a minimum working temperature exceeding -10°C be selected, the qualities required of the materials shall be satisfied at -10°C.

(*b*) The manufacturer shall also take account of the following provisions:

(i) it shall be possible to inspect the inside of vessels;

(ii) it shall be possible to drain the vessels;

(iii) the mechanical qualities shall be maintained throughout the period of use of the vessel for the intended purpose;

(iv) the vessels shall, bearing in mind their prescribed use, be adequately protected against corrosion.

(*c*) The manufacturer shall take account of the fact that under the conditions of use envisaged:

(i) the vessels shall not be subjected to stresses likely to impair their safety in use;

(ii) internal pressure shall not permanently exceed the maximum working pressure PS. However, it may momentarily do so by up to

10%.

(*d*) Circumferential and longitudinal seams shall be made using full penetration welds or welds of equivalent effectiveness. Convex ends other than hemispherical ones shall have a cylindrical edge.

2.1. *Wall thickness*

If the product of PS × V is not more than 3 000 bar.L, the manufacturer shall select one of the methods described in points 2.1.1 and 2.1.2 for determining vessel wall thickness; if the product of PS × V is more than 3 000 bar.L, or if the maximum working temperature exceeds 100°C, such thickness shall be determined by the method described in point 2.1.1.

The actual wall thickness of the cylindrical section and ends shall, however, be not less than 2 mm in the case of steel vessels and not less than 3 mm in the case of aluminium or aluminium alloy vessels.

2.1.1. Calculation method

The minimum thickness of pressurised parts shall be calculated having regard to the intensity of the stresses and to the following provisions:

(*a*) the calculation pressure to be taken into account shall not be less than the maximum working pressure PS selected;

(*b*) the permissible general membrane stress shall not exceed the lower of the values 0.6 R_{eT} or 0.3 R_m. The manufacturer shall use the R_{eT} and R_m minimum values guaranteed by the producer of the material in order to determine the permissible stress.

However, where the cylindrical portion of the vessel has one or more longitudinal welds made using a non-automatic welding process, the thickness calculated as referred to in the first paragraph shall be multiplied by the coefficient 1.15.

2.1.2. Experimental method

Wall thickness shall be so determined as to enable the vessels to resist at ambient temperature a pressure equal to at least five times the maximum working pressure, with a permanent circumferential deformation factor of no more than 1%.

3. Manufacturing processes

Vessels shall be constructed and subjected to production checks in accordance with points 2, 3 or 4 of Schedule II.

3.1. *Preparation of the component parts*

Preparation of the component parts (for example forming and chamfering) shall not give rise to surface defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the vessels.

3.2. *Welds on pressurised parts*

The characteristics of welds and adjacent zones shall be similar to those of the welded materials and shall be free of any surface or internal defects detrimental to the safety of the vessels.

Welds shall be performed by qualified welders or operators possessing the appropriate level of competence, in accordance with approved welding processes. Such approval and qualification tests shall be carried out by notified bodies.

The manufacturer shall also, during manufacture, ensure consistent weld quality by conducting appropriate tests using adequate procedures. These tests shall be the

subject of a report.

4. Putting into service of the vessels

Vessels shall be accompanied by the instructions drawn up by the manufacturer, as referred to in point 2 of Schedule III.

Schedule II

CONFORMITY ASSESSMENT PROCEDURES

1. EU-Type examination (Module B)

1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a vessel and verifies and attests that the technical design of the vessel meets the requirements of these regulations that apply to it.

1.2. EU-type examination shall be carried out in either of the following manners in accordance with regulation 15:

- assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of a prototype, representative of the production envisaged, of the complete vessel (production type),
- assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a prototype vessel (design type).

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

The application shall include:

(*a*) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(*b*) a written declaration that the same application has not been lodged with any other notified body;

(*c*) the technical documentation. The technical documentation shall make it possible to assess the vessel's conformity with the applicable requirements of these regulations 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 vessel. The technical documentation shall contain, wherever applicable, at least the following elements:

(i) a general description of the vessel;

(ii) conceptual design and manufacturing drawings and schemes of components, etc.;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the vessel;

(iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the Official Journal of

the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these regulations, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out, etc.;

(vi) test reports;

(vii) the instructions and safety information referred to in point 2 of Schedule III;

(viii) a document describing:

- the materials selected,
- the welding processes selected,
- the checks selected,
- any pertinent details as to the vessel design;

(*d*) where applicable, the prototype vessels representative of the production envisaged. The notified body may request further prototype vessels if needed for carrying out the test programme;

(*e*) 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 in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

When a prototype vessel is examined, the technical documentation shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed or a description of the proposed checks.

1.4. The notified body shall:

For the vessel:

1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the vessel.

For the prototype vessel(s):

1.4.2. verify that the prototype vessel(s) has/have been manufactured in conformity with the technical documentation, that it may safely be used under its intended working conditions 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 in accordance with other relevant technical specifications;

1.4.3. carry out appropriate examinations and tests, or have them carried out, to

check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, 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 these regulations;

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

1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 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.

1.6. Where the type meets the requirements of these regulations, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate 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. The EU-type examination certificate may have one or more Schedules attached.

The EU-type examination certificate and its Schedules shall contain all relevant information to allow the conformity of manufactured vessels with the examined type to be evaluated and to allow for in-service control. It shall also indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved type.

Where the type does not satisfy the applicable requirements of these regulations, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

1.7. 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 these regulations, 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 of all modifications to the approved type that may affect the conformity of the vessel with the essential safety requirements of these regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

1.8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such 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 and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such 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 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, its Schedules and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

1.9. The manufacturer shall keep a copy of the EU-type examination certificate, its Schedules and additions together with the technical documentation at the disposal of the national authorities for 10 years after the vessel has been placed on the market.

1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

2. Conformity to type based on internal production control plus supervised vessel testing (Module C1)

2.1. Conformity to type based on internal production control plus supervised vessel testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2, 2.3 and 2.4, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of these regulations that apply to them.

2.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of these regulations that apply to them.

Before commencing manufacture, the manufacturer shall provide a notified body of his choice with all necessary information, and in particular:

(*a*) the technical documentation, which shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed;

(*b*) the inspection document, describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

(*c*) the EU-type examination certificate.

2.3. Vessel checks

2.3.1. For each individual vessel manufactured, the notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the vessel with the type described in the EU-type examination certificate and with the corresponding requirements of these regulations in accordance with the following points:

(*a*) The manufacturer shall present his vessels in the form of uniform batches and shall take all necessary measures in order that the

manufacturing process ensures the uniformity of each batch produced.

(b) When a batch is examined, the notified body shall ensure that the vessels have been manufactured and checked in accordance with the technical documentation, and shall perform a hydrostatic test or a pneumatic test of equivalent effect on each vessel in the batch at a pressure Ph equal to 1.5 times the vessel's design pressure in order to check its strength. The pneumatic test shall be subject to acceptance of the test safety procedures by the Member State in which the test is performed.

(*c*) Moreover, the notified body shall carry out tests on test-pieces taken from a representative production test- piece or from a vessel, as the manufacturer chooses, in order to examine the weld quality. The tests shall be carried out on longitudinal welds. However, where differing weld techniques are used for longitudinal and circumferential welds, the tests shall be repeated on the circumferential welds.

(*d*) For the vessels subject to the experimental method referred to in point 2.1.2 of Schedule I, these tests on test- pieces shall be replaced by a hydrostatic test on five vessels taken at random from each batch in order to check that they conform to the essential safety requirements set out in point 2.1.2 of Schedule I.

(*e*) In the case of accepted batches, the notified body shall affix its identification number, or cause that number to be affixed, to each vessel and shall draw up a written certificate of conformity relating to the tests carried out. All vessels in the batch may be placed on the market except for those which have not successfully undergone a hydrostatic test or a pneumatic test.

(*f*) If a batch is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

(*g*) The manufacturer shall be able to supply on request by the relevant authorities the notified body's certificates of conformity referred to in point (*e*).

2.3.2. The notified body shall supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

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

2.4. CE marking and EU declaration of conformity

2.4.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these regulations.

2.4.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.

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

2.5. Authorised representative

The manufacturer's obligations set out in point 2.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

3. Conformity to type based on internal production control plus supervised vessel checks at random intervals (Module C2)

3.1. Conformity to type based on internal production control plus supervised vessel checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.3 and 3.4, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of these regulations that apply to them.

3.2. Manufacturing

3.2.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of these regulations that apply to them.

3.2.2. Before commencing manufacture, the manufacturer shall provide a notified body of his choice with all necessary information, and in particular:

(*a*) the technical documentation, which shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed;

(*b*) the EU-type examination certificate;

(*c*) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate.

The notified body shall, before the date on which any manufacture begins, examine those documents in order to certify their conformity with the EU-type examination certificate.

3.2.3. The document referred to in point (*c*) of point 3.2.2 shall include:

(*a*) a description of the means of manufacture and checking appropriate to the construction of the vessels;

(*b*) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

(*c*) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1.5 times the design pressure; those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report;

(*d*) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

3.3. Vessel checks

The notified body shall carry out vessel checks or have them carried out on random samples at random intervals determined by the body, in order to verify the quality of the internal checks on the vessel, taking into account, inter alia, the technological complexity of the vessels and the quantity of production. An adequate sample of the final vessels, 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 set out in other relevant technical specifications, shall be carried out to check the conformity of the vessel with the type described in the EU-type examination certificate and with the relevant requirements of these regulations.

The notified body shall also ensure that the manufacturer actually checks series-produced vessels in accordance with point (*c*) of point 3.2.3.

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

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the vessel performs within acceptable limits, with a view to ensuring conformity of the vessel.

The notified body shall supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

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

3.4. CE marking and EU declaration of conformity

3.4.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these regulations.

3.4.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.

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

3.5. Authorised representative

The manufacturer's obligations set out in point 3.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

4. Conformity to type based on internal production control (Module C)

4.1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.3, and ensures and declares that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of these regulations that apply to them.

4.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the approved type described in the EU-type examination certificate and with the

requirements of these regulations that apply to them.

Before commencing manufacture, the manufacturer shall provide the notified body which issued the EU-type examination certificate with all necessary information, and in particular:

(*a*) the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators;

(*b*) the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel;

(*c*) a report on the examinations and tests performed;

(*d*) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate.

That document shall include:

(i) a description of the means of manufacture and checking appropriate to the construction of the vessels;

(ii) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

(iii) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1.5 times the design pressure; those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report;

(iv) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

The notified body shall, before the date on which any manufacture begins, examine those documents in order to certify their conformity with the EU-type examination certificate.

4.3. CE marking and EU declaration of conformity

4.3.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these regulations.

4.3.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.

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

4.4. Authorised representative

The manufacturer's obligations set out in point 4.3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Schedule III

INSCRIPTIONS, INSTRUCTIONS, DEFINITIONS AND SYMBOLS

1. CE marking and inscriptions

1.1. Vessels of which the product of PS × V exceeds 50 bar.L must bear the CE marking provided for in Schedule II of Regulation (EC) No 765/2008 and the last two digits of the year in which the CE marking was affixed.

1.2. Vessels or their data plates shall bear at least the following information:

(*a*) the maximum working pressure (PS in bar);

(*b*) the maximum working temperature (T max in °C);

(*c*) the minimum working temperature (T min in °C);

(*d*) the capacity of the vessel (V in L);

(*e*) the name, registered trade name or registered trade mark and the address of the manufacturer;

(*f*) the type and serial or batch identification of the vessel.

1.3. Where the data plate is used, it shall be so designed that it cannot be reused and shall include a vacant space to enable other information to be provided.

2. Instructions and safety information

The instructions shall contain the following information:

(*a*) the particulars given in point 1.2 except for the vessel's serial or batch identification

(*b*) the intended use of the vessel;

(*c*) the maintenance and installation requirements for vessel safety.

3. Definitions and symbols

3.1. Definitions

(*a*) The design pressure 'P' is the gauge pressure chosen by the manufacturer and used to determine the thickness of the vessel's pressurised parts.

(*b*) The maximum working pressure 'PS' is the maximum gauge pressure which may be exerted under normal conditions of use of the vessel.

(*c*) The minimum working temperature T_{min} is the lowest stabilised temperature which the wall of the vessel may attain under normal conditions of use.

(*d*) The maximum working temperature T_{max} is the highest stabilised temperature which the wall of the vessel may attain under normal conditions of use.

(*e*) The yield strength 'R_{eT}' is the value at the maximum working temperature T max of any of the following:

(i) the upper yield point R_{eH}, for a material with both a lower and an upper yield point;

(ii) the 0.2% proof strength $R_{p0.2}$;

(iii) the 1.0% proof strength $R_{p1,0}$ in the case of non-alloy aluminium.

(*f*) Families of vessels:

Vessels form part of the same family if they differ from the prototype only in diameter, provided that the permissible requirements referred to in points 2.1.1 and 2.1.2 of Schedule I are complied with, and/or in the length of their cylindrical portion within the following limits:

(i) where a prototype has one or more shell rings in addition to the ends, variants shall have at least one shell ring;

(ii) where a prototype has just two dished ends, variants shall have no shell rings.

Variations in length causing the apertures and/or penetrations to be modified shall be shown in the drawing for each variant.

(*g*) A batch of vessels consists at the most of 3 000 vessels of the model of the same type.

(*h*) There is series manufacture within the meaning of these regulations if more than one vessel of the same type is manufactured during a given period by a continuous manufacturing process, in accordance with a common design and using the same manufacturing processes.

(*i*) Inspection slip: document by which the producer of the materials certifies that the products delivered meet the requirements of the order and in which he sets out the results of the routine in-plant inspection test, in particular chemical composition and mechanical characteristics, performed on products made by the same production process as the supply, but not necessarily on the products delivered.

3.2. Symbols

A	elongation after fracture ($L_o = 5{,}65\sqrt{S_o}$)	%
$A_{80\ mm}$	elongation after fracture (L_o = 80 mm)	%
KCV	bending rupture energy	J/cm^2
P	design pressure	Bar
PS	maximum working pressure	Bar
Ph	hydrostatic or pneumatic test pressure	Bar
$R_{p0.2}$	0.2% proof strength	N/mm^2
R_{eT}	yield strength at maximum working temperature	N/mm^2
R_{eH}	upper yield point	N/mm^2
R_m	tensile strength	N/mm^2
$R_{m,\ max}$	maximum tensile strength	N/mm^2
$R_{p1,0}$	1.0% proof strength	N/mm^2
T_{max}	maximum working temperature	°C
T_{min}	minimum working temperature	°C
V	capacity of the vessel	L

Schedule IV

EU DECLARATION OF CONFORMITY (No XXXX) (*)

1. Vessel/vessel model (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 the vessel allowing traceability; it may, where necessary for the identification of the vessel, include an image):

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. The notified body … (name, number) performed … (description of intervention) and issued the certificate:

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

* It is optional for the manufacturer to assign a number to the declaration of conformity.