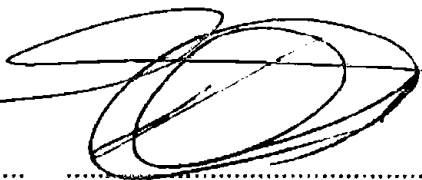



.....
Prime Minister


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Minister for European Funds,
Social Dialogue and
Consumer Protection

**- REVIEWED -
LEGISLATION UNIT**


.....
Director General
(Technical Regulations)

L.N. _____ of 2026

**PRODUCT SAFETY ACT
(CAP. 427)**

**Various Laws relating to Internal Market Emergency Procedures
for Market Surveillance and Conformity Assessment
(Amendment) Regulations, 2026**

IN EXERCISE of the powers conferred by articles 38 and 40 of the Product Safety Act, the Minister responsible for consumer affairs, in consultation with the Director General (Technical Regulations), has made the following regulations:-

1. (1) The title of these regulations is the Various Laws relating to Internal Market Emergency Procedures for Market Surveillance and Conformity Assessment (Amendment) Regulations, 2026. Citation, scope and commencement.

(2) The scope of these regulations is to transpose:

(a) Directive (EU) 2024/2839 of the European Parliament and of the Council of 23 October 2024 amending

Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU as regards certain reporting requirements in the fields of food and food ingredients, outdoor noise, patients' rights, and radio equipment; and

(b) Directive (EU) 2024/2749 of the European Parliament and of the Council of 9 October 2024 amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regards emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency.

(3) These regulations shall be deemed to have come into force on 30th May 2026:

Provided that regulation 10 shall be deemed to have come into force on 29th November 2025.

Part I

Amendments to the Simple Pressure Vessels Regulations

Amendments to
the Simple
Pressure Vessels
Regulations.
S.L. 427.01.

2. This Part amends the Simple Pressure Vessels Regulations and shall be read and construed as one with the Simple Pressure Vessels Regulations, hereinafter referred to as the "principal regulations".

Amends
regulation 4 of
the principal
regulations.

3. Regulation 4 of the principal regulations shall be amended as follows:

(a) immediately after the definition "CE Marking" there shall be added the following new definition:

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

(b) immediately after the definition "conformity assessment" there shall be added the following new definition:

" "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;";

(c) immediately after the definition "harmonised standard" there shall be added the following new definition:

" "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;";

(d) immediately after the definition "importer" there shall be added the following new definition:

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

(e) immediately after the definition "national accreditation body" there shall be added the following new definition:

" "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;";

(f) immediately after the definition "recall" there shall be added the following new definition:

" "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);";

(g) immediately after the definition "technical specifications" there shall be added the following new definition:

Cap. 510.

Adds new regulations to the principal regulations.

- " "Technical Regulations Division" or "TRD" means the Technical Regulations Division established under Part VI of the Malta Competition and Consumer Affairs Authority Act;"
4. Immediately after regulation 22 of the principal regulations there shall be added the following new regulations:

"Application of emergency procedures.

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) of these regulations 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.

22B. (1) The provisions of this regulation shall apply to vessels referred to in regulation 22A(1) and which is 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.

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 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 regulation 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.

(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.

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.

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."

Part II

Amendments to the Noise Emission in the Environment by Equipment for Use Outdoors Regulations

5. This Part amends the Noise Emission in the Environment by Equipment for Use Outdoors Regulations and shall be read and construed as one with the Noise Emission in the Environment by Equipment for Use Outdoors Regulations, hereinafter referred to as the "principal regulations".

Amendments to the Noise Emission in the Environment by Equipment for Use Outdoors Regulations.
S.L. 427.19.

Amends
regulation 1.2.
of the principal
regulations.

6. In the last proviso of regulation 1.2, the words "Malta Standards Authority" shall be substituted by the words "the Technical Regulations Division".

Substitutes
regulation 3.1.
of the principal
regulations.

7. Regulation 3.1. of the principal regulations shall be substituted by the following new regulation:

"Interpretation.

3.1. In these regulations, unless the context otherwise requires:

Cap. 427.

"Act" means the Product Safety Act;

"CE marking" means the CE conformity marking consisting of the symbol "CE" as provided in Schedule IV;

"conformity assessment body" means a body which performs conformity assessment procedures in terms of regulation 9;

"conformity assessment procedures" means the procedures which are established in Schedules V to VIII and carried out in accordance with regulation 9;

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

"Directive" means Council Directive 2000/14/ EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning the noise emission in the environment by equipment for use outdoors;

"equipment for use outdoors" or "equipment" means all machinery defined in Article 1(2) of Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery which is:

(a) either self-propelled or can be moved and which, irrespective of the driving element or elements, shall be intended, according to its type, for use in the open air and which contributes to environmental noise exposure; and

(b) non-powered equipment for industrial or environmental applications, which according to its type shall be intended to be used outdoors and which contributes to environmental noise exposure:

Provided that the use of equipment in an ambience where the transmission of sound shall not be significantly affected, for instance under tents, under roofs for protection against rain or in the shell of houses shall be regarded as use in the open air.

Cap. 460.

"European Union" or "Union" shall have the same meaning as assigned to it in the European Union Act;

"guaranteed sound power level" means a sound power level determined in accordance with the requirements established in Schedule III, which includes the uncertainties due to production variation and measurement procedures and where the manufacturer, or his authorised representative, confirms that according to the technical instruments applied and referred to in the technical documentation it is not exceeded;

"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 equipment covered by these regulations;

"internal market emergency mode" shall have the same meaning assigned to it in accordance with sub-article (3) of Article 3 of Regulation (EU) 2024/2747;

"Malta" shall have the same meaning as assigned to it in the Act;

"measured sound power level" means a sound power level as determined from measurements as carried out in accordance with Schedule III and measured values may be determined either from a single machine representative for the type of equipment or from the average of a number of machines;

"notified body" means a conformity assessment body which has been officially designated by the national authority and notified to the Commission to carry out the procedures for conformity assessment of certain products in accordance with regulation 9 before being placed on the market;

"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);

"sound power level L_{WA} " means the A-weighted sound power in dB in relation to 1 pW as defined in EN ISO 3744:1995 and EN ISO 3746:1995;

Cap. 510.

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

3.2. Unless otherwise required under these regulations, the terms defined in Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 and the Act shall apply."

Substitutes
regulation 5.2.
of the principal
regulations.

8. Regulation 5.2. of the principal regulations shall be substituted by the following new regulation:

"5.2. Where neither the manufacturer nor his authorised representative is established in the Union, the obligations of these regulations shall apply to the importer or to any person putting the equipment into service in Malta."

Amends
regulation 10.1.
of the principal
regulations.

9. In regulation 10.1. of the principal regulations the words "The Director of Consumer Affairs" shall be substituted by the words "The TRD".

Amends
regulation 10.3.
of the principal
regulations.

10. In regulation 10.3. of the principal regulations the words "the Director of Consumer Affairs shall take all appropriate measures so that the manufacturer or his authorized representative shall bring the equipment into conformity with the provisions of these regulations, and shall so inform the Consumer and Industrial Goods Directorates of the Malta Standards Authority." shall be substituted by the words "the TRD shall take all appropriate measures so that the manufacturer or his

authorised representative shall bring the equipment into conformity with the provisions of these regulations."

11. In regulation 10.4. of the principal regulations the words "the Director of Consumer Affairs shall take all appropriate measures to restrict or prohibit the placing on the market or putting into service of the equipment in question or to ensure that it is withdrawn from the market, and shall so inform the Consumer and Industrial Goods Directorate of the Malta Standards Authority." shall be substituted by the words "the TRD shall take all appropriate measures to restrict or prohibit the placing on the market or putting into service of the equipment in question or to ensure that it is withdrawn from the market.".

Amends
regulation 10.4.
of the principal
regulations.

12. In regulation 10.5. of the principal regulations the words "the Director of Consumer Affairs shall take appropriate action against whomsoever has affixed the marking or drawn up the declaration and shall so inform the Consumer and Industrial Goods Directorate of the Malta Standards Authority." shall be substituted by the words "the TRD shall take appropriate action against whosoever has affixed the marking or drawn up the declaration.".

Amends
regulation 10.5.
of the principal
regulations.

13. Regulations 10.7. and 10.8. of the principal regulations shall be deleted.

Deletes
regulations 10.7.
and 10.8. of the
principal
regulations.

14. Immediately after regulation 12.1. of the principal regulations there shall be added the following new regulations:

Adds new
regulations to
the principal
regulations.

"Application of
emergency
procedures.

12A. (1) The TRD shall ensure that measures shall be taken in accordance with regulations 12B and 12C during the activation of the internal market emergency mode in terms of 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 equipment covered by these regulations. The emergency procedures relevant to Union product legislation may be activated only as regards those crisis-relevant goods as defined by these regulations.

(2) Regulations 12B and 12C shall apply only to equipment referred to in regulation 2.1. which has been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/2747.

(3) Regulations 12B and 12C shall apply only during the internal market emergency mode which has been activated in accordance with Article 18 of Regulation (EU) 2024/2747:

(3) The prioritisation provided in regulation 12C(5) shall apply to conformity assessment of equipment in stand-by mode and after its regulation (2) expiry on deactivation. In addition, in additional disproportionate costs for the manufacturers who have filed those applications. The notified bodies shall take all reasonable measures to increase their testing capacity for equipment referred to in sub-regulation 9.1. and which (1) regarding which they have been notified.

Derogation from the conformity assessment procedures requiring the mandatory involvement of a notified body.

12C. (1) By way of derogation from regulation 9, the TRD may authorise an application for a conformity assessment from an economic operator placing on the market or putting into service in Malta of specific equipment before listed in Schedule XI and referred to in regulation 12A(1), for which the conformity assessment procedures referred to in regulation 9 which require the mandatory involvement of a notified body have not been carried out:

Provided that compliance with all the applicable requirements provided in these regulations concerning noise emission in the environment has been demonstrated in accordance with the 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 equipment subject to the extension of validity 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 prioritisation of applications for a conformity assessment of equipment pursuant to sub-regulation (2) shall not result in additional disproportionate costs for the manufacturers who have filed those applications. The notified bodies shall take all reasonable measures to increase their testing capacities for equipment referred to in sub-regulation (1) regarding which they have been notified.

Derogation from the conformity assessment procedures requiring the mandatory involvement of a notified body.

12C. (1) By way of derogation from regulation 9, the TRD may authorise, on a duly justified request from an economic operator, the placing on the market or putting into service in Malta of specific equipment listed in Schedule XI and referred to in regulation 12A(1), for which the conformity assessment procedures referred to in regulation 9 which require the mandatory involvement of a notified body have not been carried out:

Provided that compliance with all the applicable requirements provided in these regulations concerning noise emission in the environment has been demonstrated in accordance with the 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 equipment subject to the extension of validity 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.

(5) Manufacturers of equipment subject to the authorisation procedure referred to in sub-regulation (1) shall declare on their sole responsibility that the equipment concerned complies with all the applicable requirements established in these regulations concerning noise emission in the environment and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the TRD.

(6) Any authorisation issued pursuant to sub-regulation (1) shall provide for the conditions and requirements under which the equipment may be placed on the market or put into service in Malta. The authorisations shall provide at least the following requirements:

(a) a description of the procedures by means of which compliance with the applicable requirements of these regulations concerning noise emission in the environment was successfully demonstrated;

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

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

(7) By way of derogation from regulations 6 and 11, equipment for which an authorisation has been granted in accordance with sub-regulation (1) shall not bear the CE marking and regulation 6 shall not apply.

S.L. 427. 105.

(8) Where an authorisation pursuant to sub-regulations (1) and (3) is valid, the TRD shall with respect to the equipment, take all the corrective and restrictive actions provided for in accordance with the Market Surveillance and Compliance of Products Regulations and these regulations. The TRD shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

(9) The use of the authorisation procedure provided in sub-regulations (1) and (3) shall not affect the application of the relevant conformity assessment procedures established in regulation 9."

15. In Schedule II to the principal regulations the words "Community Directives" shall be substituted by the words "European Union Directives".

Amends
Schedule II to
the principal
regulations.

Part III

Amendments to the Pressure Equipment Regulations

16. This Part amends the Pressure Equipment Regulations and shall be read and construed as one with the Pressure Equipment Regulations, hereinafter referred to as the "principal regulations".

Amendments to
the Pressure
Equipment
Regulations.
S.L. 427.29.

17. Regulation 4 of the principal regulations shall be amended as follows:

Amends
regulation 4 of
the principal
regulations.

(a) immediately after the definition "CE marking" there shall be added the following new definition:

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

(b) immediately after the definition "conformity assessment" there shall be added the following new definition:

" "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 in accordance with Article 18(4) of Regulation (EU) 2024/

2747 with respect to equipment covered by these regulations;";

(c) immediately after the definition "harmonised standard" there shall be added the following new definition:

" "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 in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to equipment covered by these regulations;";

(d) immediately after the definition "importer" there shall be added the following new definition:

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

(e) immediately after the definition "nominal size (DN)" there shall be added the following new definition:

" "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 16 before being placed on the market;";

(f) immediately after the definition "recall" there shall be added the following new definition:

" "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);".

Adds new regulations to the principal regulations.

18. Immediately after regulation 29 of the principal regulations

there shall be added the following new regulations:

"Application of
emergency
procedures.

29A. (1) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 29B to 29E apply only during the activation of the internal market emergency procedure in accordance with Article 28 of Regulation (EU) 2024/2747 and by means of an implementing act in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to pressure equipment and assemblies covered by these regulations. The emergency procedures relevant to Union harmonisation legislation may be activated as regards those crisis-relevant goods as defined by these regulations.

(2) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 29B to 29E apply only to pressure equipment and assemblies which have been designated as crisis-relevant goods in accordance with to Article 18(4) of Regulation (EU) 2024/2747.

(3) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 29B to 29E apply only during the internal market emergency mode which has been activated in accordance with Article 18 of Regulation (EU) 2024/2747:

Provided that regulation 29C(6) shall apply during the internal market emergency mode and after its expiry or deactivation.

Prioritisation of the
conformity
assessment of
pressure equipment
and assemblies
designated as
crisis-relevant
goods.

29B. (1) The provisions of this regulation shall apply to pressure equipment or assemblies referred to in regulation 29A(1) and which are subject to the conformity assessment procedures referred to in regulation 16 and which require the mandatory involvement of a notified body.

(2) The notified bodies shall as a matter of priority take all appropriate measures to process all applications for a conformity assessment of pressure equipment and assemblies referred to in sub-regulation (1), irrespective of whether those applications have been filed before or after the activation of the emergency procedures.

(3) The prioritisation of applications for conformity assessment of pressure equipment and assemblies 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 pressure equipment and assemblies 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.

29C. (1) By way of derogation from regulation 16, the Technical Regulations Division may authorise, following a duly justified request from an economic operator, the placing on the market or use for the manufacturer's own purposes in Malta, of specific pressure equipment or assembly referred to in regulation 29A(1) for which the conformity assessment procedures referred to in regulation 16 which require the mandatory involvement of a notified body have not been carried out:

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

(2) The pressure equipment or assemblies subject to the extension of validity referred to in sub-regulation (1) shall bear the information that they are placed on the market or used for the manufacturer's own purposes 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 Technical Regulations Division 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 and the TRD shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

(4) Manufacturers of pressure equipment or assemblies subject to the extension of validity of the authorisation procedure referred to in sub-regulation (1) shall declare on their sole responsibility that the pressure equipment or assembly concerned complies with all the applicable essential safety requirements established in Schedule I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the Technical Regulations Division.

(5) Any authorisation issued in accordance with sub-regulation (1) shall establish the conditions and requirements under which the pressure equipment or assembly may be placed on the market or used for the manufacturer's own purposes. Such authorisations shall establish at least the following:

(a) a description of the procedures by means of which compliance with the applicable essential safety requirements established in Schedule I was successfully demonstrated;

(b) any specific requirements regarding the traceability of the pressure equipment or assembly concerned;

(c) an end date of validity of the authorisation, which shall not 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 pressure equipment or assembly concerned;

(e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the pressure equipment or assembly concerned that has been placed on the market or used for the manufacturer's own purposes.

(6) By way of derogation from regulations 7, 20 and 21, pressure equipment or assemblies for which an authorisation has been granted in accordance with sub-regulation (1) shall not bear the CE marking and regulation 7 shall not apply.

S.L. 427.105.

Presumption of
conformity based
on standards and
common
specifications.

(7) Where an authorisation pursuant to sub-regulations (1) and (3) is valid, the Technical Regulations Division shall, with respect to such pressure equipment or assemblies, take all corrective and restrictive actions provided for under the Market Surveillance and Compliance of Products Regulations. The Technical Regulations Division shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

(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 16.

29D. (1) Without prejudice to regulation 14, pressure equipment or assemblies which are in conformity with the harmonised standards or common specifications or parts thereof referred to in these regulations shall be presumed to be in conformity with the applicable essential safety requirements established in Schedule I 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 referred to in sub-regulation (1).

(3) By way of derogation from 29A(3), unless there is sufficient reason to believe that the pressure equipment and assemblies 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 pressure equipment and assemblies which are in conformity with those standards or common specifications and which have been placed on the market or used for the manufacturer's own purposes shall be deemed to be in conformity with the applicable essential safety requirements established in Schedule I after the expiry or deactivation of the internal market emergency mode."

(4) When the Technical Regulations Division considers that a standard or common specification as referred to in sub-regulation (1) does not entirely satisfy the applicable essential safety requirements specified in Schedule I, it shall inform the Commission by submitting a detailed explanation thereof.

Prioritisation of market surveillance activities and mutual assistance among authorities.

29E. The Technical Regulations Division 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."

Part IV

Amendments to the Transportable Pressure Equipment Regulations

19. This Part amends the Transportable Pressure Equipment Regulations, and shall be read and construed as one with the Transportable Pressure Equipment Regulations hereinafter referred to as the "principal regulations".

Amendments to the Transportable Pressure Equipment Regulations. S.L. 427.30.

20. Regulation 3 of the principal regulations shall be amended as follows:

Amends regulation 3 of the principal regulations.

(a) immediately after the definition "conformity assessment" there shall be added the following new definition:

" "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 equipment covered by these regulations;"

(b) immediately after the definition "exceptional check" there shall be added the following new definition:

" "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 equipment covered by these regulations;";

(c) immediately after the definition "intermediate inspection" there shall be added the following new definition:

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

(d) immediately after the definition "recall" there shall be added the following new definition:

" "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);".

Adds new regulations to the principal regulations.

21. Immediately after regulation 17 of the principal regulations there shall be added the following new regulations:

"Application of emergency procedures.

17A. (1) The TRD shall ensure that measures taken in accordance with regulations 17B to 17D apply only during the activation of the internal market emergency mode in accordance with Article 28 of Regulation (EU) 2024/2747 and by means of an implementing act in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to transportable pressure equipment 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 in accordance with 17B to 17D 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 in accordance with regulations 17B to 17D 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 17C(6) shall apply during the internal market emergency mode and after its expiry or deactivation.

Prioritisation of the conformity assessment of transportable pressure equipment designated as crisis-relevant goods.

17B. (1) The provisions of this regulation shall apply to transportable pressure equipment referred to in regulation 17A(1) and shall be subject to the conformity assessment procedures referred to in regulation 12 which require the mandatory involvement of a notified body.

(2) The notified bodies shall as a matter of priority, take all appropriate measures to process all applications for a conformity assessment of transportable pressure equipment referred to in sub-regulation (1), irrespective of whether those applications have been filed before or after the activation of the emergency procedures.

(3) The prioritisation of applications for a conformity assessment of transportable pressure equipment 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 necessary measures to increase their testing capacities for transportable pressure equipment 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.

17C. (1) By way of derogation from regulation 12, the TRD may authorise, on a duly justified request from an economic operator, the placing on the market in Malta, of specific vessels referred to in regulation 17A(1), for which the conformity assessment procedures referred to in regulation 12 which require the mandatory involvement of a notified body have not been carried out:

S.L. 65.22.

Provided that compliance with all the applicable requirements established in the Schedules of the Motor Vehicles (Carriage of Dangerous Goods by Road) Regulations and 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 transportable pressure equipment 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, intelligible and be written in the English or Maltese language.

(3) The authorisation granted by TRD in accordance with 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.

S.L. 65.22.

(4) Manufacturers 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 requirements established in the Schedules of the Motor Vehicles (Carriage of Dangerous Goods by Road) Regulations and 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 requirements established in the Annexes to Directive 2008/68/EC and in these regulations was successfully demonstrated;

(b) any specific requirements regarding the traceability of the transportable pressure equipment 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 transportable pressure equipment concerned; and

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

(6) By way of derogation from regulation 14, transportable pressure equipment for which an authorisation has been granted in accordance with sub-regulation (1) shall not bear the Pi marking.

(7) Where an authorisation pursuant to sub-regulations (1) and (3) is valid, the TRD shall with respect to such transportable pressure equipment, take all corrective and restrictive actions provided for under the Market Surveillance and Compliance of Products 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.

(8) The use of the authorisation procedure established in sub-regulations (1) and (2) shall not affect the application of the relevant conformity assessment procedures established in regulation 12.

S.L. 427.105.

Prioritisation of market surveillance activities and mutual assistance among authorities.

17D. 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."

Part V
Amendments to the Low Voltage Electrical Equipment Regulations

Amendments to
the Low Voltage
Electrical
Equipment
Regulations.
S.L. 427:34

22. This Part amends the Low Voltage Electrical Equipment Regulations and shall be read and construed as one with the Low Voltage Electrical Equipment Regulations, hereinafter referred to as the "principal regulations".

Amends
regulation 3 of
the principal
regulations.

23. Regulation 3 of the principal regulations shall be amended as follows:

(a) immediately after the definition "CE marking" there shall be added the following new definition:

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

(b) immediately after the definition "conformity assessment" there shall be added the following new definition:

" "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 equipment covered by these regulations;"

(c) immediately after the definition "harmonised standard" there shall be added the following new definition:

" "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 in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to equipment covered by these regulations;"

(d) immediately after the definition "importer" there shall be added the following new definition:

" "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3) of Regulation (EU) 2024/2747;"; and

(e) immediately after the definition "recall" there shall be added the following new definition:

" "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);".

24. Immediately after regulation 18 of the principal regulations there shall be added the following new regulations:

Adds new regulations to the principal regulations.

"Application of emergency procedures.

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

(2) The TRD shall ensure that measures taken in accordance with regulation 18B and 18C apply only to electrical equipment which has been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/2747.

(3) The TRD shall ensure that measures taken in accordance with regulation 18B and 18C apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/2747.

Presumption of conformity based on harmonised standards and common specifications.

18B. (1) Without prejudice to regulations 12, 13 and 14, electrical equipment which is in conformity with the harmonised standards or common specifications or parts thereof referred to in these regulations, shall be presumed to be in conformity with the safety objectives referred to in regulation 5 and established in Schedule I 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 referred to sub-regulation (1).

(3) By way of derogation from regulation 18A(3), unless there is sufficient reason to believe that electrical equipment 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 electrical equipment which is in conformity with those standards or common specifications and which has been placed on the market shall be deemed to be in conformity with the safety objectives referred to in regulation 5 and established in Schedule I after the expiry or deactivation of the internal market emergency mode."

(4) When the TRD considers that a standard or common specification referred to in sub-regulation (1) does not entirely satisfy the safety objectives referred to in sub-regulation (3) and specified in Schedule I, it shall inform the Commission by submitting a detailed explanation thereof.

Mutual assistance among authorities.

18C. 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."

Part VI

Amendments to the Electromagnetic Compatibility Regulations

Amendments to the Electro-magnetic Compatibility Regulations. S.L. 427.35.

25. This Part amends the Electromagnetic Compatibility Regulations and shall be read and construed as one with the Electromagnetic Compatibility Regulations, hereinafter referred to as the "principal regulations".

26. Regulation 2 of the principal regulations shall be amended as follows:

Amends
regulation 2 of
the principal
regulations.

(a) immediately after the definition "CE marking" there shall be added the following new definition:

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

(b) immediately after the definition "conformity assessment body" there shall be added the following new definitions:

" "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 in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to equipment covered by these regulations;"

(c) immediately after the definition "immunity" there shall be added the following new definition:

" "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 in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to equipment covered by these regulations;"

(d) immediately after the definition "importer" there shall be added the following new definition:

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

(e) immediately after the definition "national accreditation body" there shall be added the following new definition:

" "notified body" means a conformity assessment body which has been officially designated by its national authority and notified to the European Commission to carry out the procedures for conformity assessment of certain products in terms of regulation 14 before being placed on the market;"

(f) immediately after the definition "recall" there shall be added the following new definition:

" "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);".

Adds new regulations to the principal regulations.

27. Immediately after regulation 36 of the principal regulations there shall be added the following new regulations:

"Application of emergency procedures.

36A. (1) The TRD shall ensure that measures taken pursuant to regulation 36B and 36C apply only during the activation of the internal market emergency mode in terms of Article 28 of Regulation (EU) 2024/2747 and by means of an implementing act in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to apparatus 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 in accordance with regulation 36B and 36C apply only to apparatus which have been designated as crisis-relevant goods in accordance with Article 18(4) of Regulation (EU) 2024/2747.

(3) The TRD shall ensure that measures taken pursuant to regulation 36B apply solely during the internal market emergency mode which has been activated in accordance with Article 18 of Regulation (EU) 2024/2747.

Presumption of conformity based on harmonised standards and common specifications.

36B. (1) Without prejudice to regulation 13, apparatus which is in conformity with the harmonised standards or common specifications or parts thereof referred to in these regulations, shall be presumed to be in conformity with the essential requirements established in Schedule I 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 referred to in sub-regulation (1).

(3) By way of derogation from regulation 36A(3), unless there is sufficient reason to believe that the apparatus 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 apparatus which is 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 requirements established in Schedule I after the expiry or deactivation of the internal market emergency mode.

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

Prioritisation of market surveillance activities and mutual assistance among authorities.

36C. 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."

Part VII Amendments to the Machinery Regulations

28. This Part amends the Machinery Regulations and shall be read and construed as one with the Machinery Regulations, hereinafter referred to as the "principal regulations".

Amendments to the Machinery Regulations
S.L. 427. 36.

29. Regulation 3 of the principal regulations shall be amended as follows:

Amends regulation 3 of the principal regulations.

(a) in the marginal note thereof the words "Definitions." shall be substituted by the words "Interpretation.";

(b) the definition "the Community" shall be substituted by the following new definition:

"Community" means the European Union;"

(c) immediately after the definition "Community", as amended, there shall be added the following new definitions:

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

"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 machinery covered by these regulations;"

(d) immediately after the definition "harmonized standard" there shall be added the following new definition:

" "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 in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to machinery covered by these regulations;"

(e) immediately after the definition "interchangeable equipment" there shall be added the following new definition:

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

(f) the definition "Market Surveillance Directorate" shall be substituted by the following new definition:

" "Market Surveillance Directorate" means the Market Surveillance Directorate within the TRD;"

(g) immediately after the definition "manufacturer" there shall be added the following new definition:

" "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 terms of regulation 13 before being placed on the market;"

(h) immediately after the definition "putting into service" there shall be added the following new definition:

" "Regulation (EU) 2024/2747" means Regulation 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);"

(i) the definition "Regulatory Affairs Directorate" shall be deleted;

(j) in the definition "safety component" the words "Schedule V." shall be substituted by the words "Schedule V;" and immediately thereafter there shall be added the following new definition:

" "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.

30. Regulation 9 of the principal regulations shall be amended as follows:

Amends
regulation 9 of
the principal
regulations.

(a) in sub-regulation (1) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD"; and

(b) in sub-regulation (2) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD".

Amends
regulation 10 of
the principal
regulations.

31. Regulation 10 of the principal regulations shall be amended as follows:

(a) in sub-regulation (2) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD";

(b) in sub-regulation (3) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD"; and

(c) in sub-regulation (4) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD".

Amends
regulation 13 of
the principal
regulations.

32. Regulation 13 of the principal regulations shall be amended as follows:

(a) in sub-regulation (1) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD";

(b) in sub-regulation (2) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD";

(c) in sub-regulation (3) thereof the words "the Regulatory Affairs Directorate" shall be substituted by the words "the TRD";

(d) in sub-regulation (4) thereof the words "Bodies" shall be substituted by the words "Notified bodies";

(e) in sub-regulation (5) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD"; and

(f) in sub-regulation (6) thereof the words "the Regulatory Affairs Directorate", wherever they occur, shall be substituted by the words "the TRD".

Amends
regulation 16 of
the principal
regulations.

33. Regulation 16 of the principal regulations shall be amended as follows:

(a) in sub-regulation (1) thereof the words "the Market Surveillance Directorate and the Regulatory Affairs Directorate" shall be substituted by the words "the TRD";

(b) in sub-regulation (2) thereof the words "the

Regulatory Affairs Directorate" shall be substituted by the words "the TRD"; and

(c) in sub-regulation (3) thereof the words "the Regulatory Affairs Directorate" shall be substituted by the words "the TRD".

34. Regulation 17 of the principal regulations shall be deleted.

Deletes regulation 17 of the principal regulations.

35. Immediately after regulation 18 of the principal regulations there shall be added the following new regulations:

Adds new regulations to the principal regulations.

"Application of emergency procedures.

18A. (1) The TRD shall ensure that measures taken in accordance with regulations 18B to 18E shall 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 machinery 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 18B to 18E shall apply only to machinery which has been designated as crisis-relevant goods in accordance with Article 18(4) of Regulation (EU) 2024/2747.

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

Provided that regulation 18C(6) shall apply during the internal market emergency mode and after its expiry or deactivation.

Prioritisation of the conformity assessment of machinery designated as crisis-relevant goods.

18B. (1) The provisions of these regulations shall apply to machinery referred to in regulation 18A(1) and which is subject to the conformity assessment procedures referred to in regulation 11 which requires the mandatory involvement of a notified body pursuant to regulation 13.

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

(3) The prioritisation of applications for a conformity assessment of machinery 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 necessary measures to increase their testing capacities for machinery 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.

18C. (1) By way of derogation from regulation 11 the TRD may authorise, on a duly justified request from an economic operator, the placing on the market or putting into service in Malta, of specific machinery referred to in regulation 18A(1) for which the conformity assessment procedures referred to in regulation 11 which require the mandatory involvement of a notified body have not been carried out:

Provided that compliance with all the applicable essential health and safety requirements provided in these regulations shall be demonstrated in accordance with procedures referred to in the respective 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 machinery, subject to the extension of validity of the authorisation pursuant to sub-regulation (1), shall bear the information that it is placed on the market or put into service as a crisis-relevant good. The information and any labelling shall be clear, intelligible and be written in the English or Maltese language.

(3) The authorisation granted by TRD in accordance with 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 of machinery subject to the authorisation procedure referred to in sub-regulation (1) shall declare on their sole responsibility that the machinery concerned complies with all the applicable essential health and safety requirements established in Schedule I 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 machinery may be placed on the market or put into service in Malta. The authorisations shall provide at least the following:

(a) a description of the procedures, by means of which compliance with the applicable essential health and safety requirements established in Schedule I was successfully demonstrated;

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

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

(6) By way of derogation from regulations 7 and 14, machinery for which an authorisation has been granted in accordance with sub-regulation (1) shall not bear the CE marking and regulation 7 shall not apply.

S.L. 427.105.

Presumption of
conformity based
on harmonised
standards and
common
specifications.

(7) Where an authorisation pursuant to sub-regulations (1) and (3) is valid the TRD shall with respect to the machinery take all corrective and restrictive actions provided for in accordance with the Market Surveillance and Compliance of Products Regulations and these regulations. The TRD shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

(8) The use of the authorisation procedure established in sub-regulations (1) and (2) shall not affect the application of the relevant conformity assessment procedures established in regulation 11.

18D. (1) Without prejudice to regulation 8, machinery which is in conformity with the harmonised standards or common specifications or parts thereof referred to in these regulations, shall be presumed to be in conformity with the relevant essential health and safety requirements established in Schedule I 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 common specifications referred to in these regulations.

(3) By way of derogation from regulation 18A(3), unless there is sufficient reason to believe that the machinery covered by the standards or common specifications referred to in sub-regulation (1) presents a risk to the health or safety of persons, the machinery which is in conformity with respective standards or common specifications and which have been placed on the market or put into service shall be deemed to be in conformity with the relevant essential health and safety requirements established in Schedule I 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 relevant essential health and safety requirements established in Schedule I, it shall inform the Commission by submitting a detailed explanation thereof.

Prioritisation of
market surveillance
activities and
mutual assistance
among
authorities.

18E. 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."

36. In item 9 of Schedule 11 of the principal regulations the words "the Regulatory Affairs Directorate" shall be substituted by the words "the TRD".

Amends
Schedule 11 of
the principal
regulations.

Part VIII Amendments to the Lifts Regulations

37. This Part amends the Lifts Regulations and shall be read and construed as one with the Lifts Regulations, hereinafter referred to as the "principal regulations".

Amendments to
the Lifts
Regulations.
S.L. 427. 37.

38. Regulation 2 of the principal regulations shall be amended as follows:

Amends
regulation 2 of
the principal
regulations.

(a) immediately after the definition "CE marking" there shall be added the following new definition:

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

(b) immediately after the definition "conformity assessment body" there shall be added the following new definition:

" "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 equipment covered by these regulations;"

(c) immediately after the definition "harmonised standard" there shall be added the following new definition:

" "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 equipment covered by these regulations;";

(d) immediately after the definition "installer" there shall be added the following new definition:

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

(e) the definition "notified body" shall be substituted by the following new definition:

" "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 pursuant to regulations 16 and 17 before being placed on the market;";

(f) immediately after the definition "recall" there shall be added the following new definition:

" "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);";

(g) immediately after the definition "technical specification" there shall be added the following new definition:

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

Cap. 510.

Adds new regulations to the principal regulations.

39. Immediately after regulation 24 of the principal regulations

there shall be added the following new regulations:

"Application of
emergency
procedures.

24A. (1) The TRD shall ensure that measures taken in accordance with regulations 24B to 24E apply only during the activation of the internal market emergency mode in accordance with Article 28 of Regulation (EU) 2024/2747 and by means of an implementing act in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to lifts and safety components for lifts 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 in accordance with regulations 24B to 24E apply only to lifts and safety components for lifts which have been designated as crisis-relevant goods in accordance with Article 18(4) of Regulation (EU) 2024/2747.

(3) The TRD shall ensure that measures taken in accordance with regulations 24B to 24E 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 24C(6) shall apply during the internal market emergency mode and after its expiry or deactivation.

Prioritisation of the
conformity
assessment of lifts
and safety
components for
lifts designated as
crisis-relevant
goods.

24B. (1) The provisions of this regulation shall apply to all lifts and safety components referred to in regulation 24A(1) and which are subject to the conformity assessment procedures referred to in regulations 15 and 16 which require the mandatory involvement of a notified body.

(2) The notified bodies shall as a matter of priority, take all necessary measures to process all applications for a conformity assessment of lifts and safety components for lifts referred to in sub-regulation (1), irrespective of whether those applications have been filed before or after the activation of the emergency procedures.

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

Derogation from the conformity assessment procedures requiring the mandatory involvement of a notified body.

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

24C. (1) By way of derogation from regulations 16 and 17, the TRD may authorise, following a duly justified request from an economic operator, the placing on the market in Malta, of a specific safety component for lifts and of a specific lift both referred to in regulation 24A(1), for which the conformity assessment procedures referred to in regulations 16 and 17 which require the mandatory involvement of a notified body, have not been carried out:

Provided that compliance with all the applicable essential health and safety requirements established in these regulations has been demonstrated in accordance with procedures referred to in that 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 lifts or the safety components for lifts subject to the extension of validity of the authorisation referred to in sub-regulation (1) shall bear the information that they are placed on the market as "crisis-relevant goods". Such information, as well as any labelling shall be clear, intelligible and, where relevant, shall be written in the English or Maltese language.

(3) The authorisation granted by TRD in accordance with 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) Installers of lifts or manufacturers of safety components for lifts subject to the authorisation procedure referred to in sub-regulation (1) shall declare on their sole responsibility that the lifts or safety components for lifts concerned comply with all the applicable essential health and safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the TRD.

(5) Any authorisation issued in accordance with sub-regulation (1) shall establish the conditions and requirements under which the lift or safety component for lifts may be placed on the market. Such authorisations shall establish at least the following:

(a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements established in Schedule I was successfully demonstrated;

(b) any specific requirements regarding the traceability of the lift or safety component for lifts concerned;

(c) an end date of validity of the authorisation, which shall not 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 lifts or safety components for lifts concerned;

(e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the lifts or safety components for lifts concerned that have been placed on the market.

(6) By way of derogation from regulations 3 and 19, lifts or safety components for lifts for which an authorisation has been granted in accordance with sub-regulations (1) shall not bear the CE marking and regulation 3 shall not apply.

(7) Where an authorisation pursuant to sub-regulations (1) (and (3) is valid, the TRD shall with respect to such lifts or safety components for lifts, take all corrective and restrictive actions in accordance with the Market Surveillance and Compliance of Products Regulations and these regulations. The TRD shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

(8) The use of the authorisation procedure established in sub-regulations (1) and (2) shall not affect the application of the relevant conformity assessment procedures provided in regulations 16 and 17.

Presumption of conformity based on harmonised standards and common specifications.

24D. (1) Without prejudice to regulation 15 lifts and safety components for lifts which are in conformity with the harmonised standards or common specifications or parts thereof referred to in these regulations shall be presumed to be in conformity with the applicable essential health and safety requirements established in Schedule I 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 installers and manufacturers to rely on the presumption of conformity provided by the harmonised standards, or the common specifications referred to in sub-regulation (1).

(3) By way of derogation from 24A(3), unless there is sufficient reason to believe that the lifts and safety components for lifts covered by the harmonised standards or common specifications referred to in subparagraph (1) present a risk to the health or safety of persons, the lifts and safety components for lifts 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 applicable essential health and safety requirements established in Schedule I after the expiry or deactivation of the internal market emergency mode.

(4) When the TRD considers that a standard or common specification referred to in sub-regulation (1) does not entirely satisfy the applicable essential health and safety requirements specified in Schedule I, it shall inform the Commission by submitting a detailed explanation thereof.

Mutual assistance among authorities.

24E. 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."

Part IX
**Amendments to the Equipment and Protective Systems intended
 for Use in Potentially Explosive Atmospheres Regulations**

40. This Part amends the Equipment and Protective Systems intended for Use in Potentially Explosive Atmospheres Regulations and shall be read and construed as one with the Equipment and Protective Systems intended for Use in Potentially Explosive Atmospheres Regulations, hereinafter referred to as the "principal regulations".

Amendments to the Equipment and Protective Systems intended for Use in Potentially Explosive Atmospheres Regulations S.I. 427.39.

41. Regulation 4 of the principal regulations shall be amended as follows:

Amends regulation 4 of the principal regulations.

(a) immediately after the definition "CE marking" there shall be added the following new definition:

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

(b) immediately after the definition "conformity assessment body" there shall be added the following new definitions:

" "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 equipment covered by these regulations;"

(c) immediately after the definition "harmonised standard" there shall be added the following new definition:

" "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 in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to equipment covered by these regulations;"

(d) immediately after the definition "intended use" there shall be added the following new definition:

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

(e) immediately after the definition "national accreditation body" there shall be added the following new definition:

" "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;" and

(f) immediately after the definition "recall" there shall be added the following new definition:

" "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);".

Adds new regulations to the principal regulations.

42. Immediately after regulation 22 of the principal regulations there shall be added the following new regulations:

"Application of emergency procedures.

22A. (1) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 22B to 22E apply only during the activation of the internal market emergency procedure 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 products covered by these regulations. The emergency procedures relevant to Union harmonisation legislation may be activated as regards those crisis-relevant goods as defined by these regulations.

(2) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 22B to 22E apply only to products which have been designated as crisis-relevant goods in accordance with Article 18(4) of Regulation (EU) 2024/2747.

(3) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 22B to 22E apply only during the internal market emergency mode which 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 products designated as crisis-relevant goods.

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

(2) The notified bodies shall as a matter of priority, take all appropriate measures to process all applications for a conformity assessment of products referred to in sub-regulation (1), irrespective of whether those applications have been filed before or after the activation of the emergency procedures.

(3) The prioritisation of applications for a conformity assessment of products in accordance with 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 products referred to 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.

22C. (1) By way of derogation from regulation 15, the Technical Regulations Division may authorise, following a duly justified request from an economic operator, the placing on the market or use for the manufacturer's own purposes in Malta, of a specific product 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 health and safety requirements established in Schedule II has been demonstrated in accordance with procedures referred to in such authorisation. The Technical Regulations Division shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with this sub-regulation.

(2) The product 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 or used for the manufacturer's own purposes as a crisis-relevant good. Such information, as well as any labelling shall be clear, intelligible, and where relevant, shall be written in the English or Maltese language.

(3) The authorisation granted by Technical Regulations Division in accordance with 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 Technical Regulations Division shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

(4) Manufacturers of products subject to the authorisation procedure referred to in sub-regulation (1) shall declare on their sole responsibility that the product concerned complies with all the applicable essential health and safety requirements established in Schedule II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the Technical Regulations Division.

(5) Any authorisation issued in accordance with sub-regulation (1) shall establish the conditions and requirements under which the product may be placed on the market or used for the manufacturer's own purposes. Such authorisations shall establish at least the following:

- (a) a description of the procedures by means of which compliance with the applicable essential health and safety requirements established in Schedule II was successfully demonstrated;
- (b) any specific requirements regarding the traceability of the product concerned;

(c) an end date of validity of the authorisation, which shall not 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 product concerned;

(e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the products concerned that have been placed on the market or used for the manufacturer's own purposes.

(6) By way of derogation from regulations 9 and 17, products for which an authorisation has been granted in accordance with sub-regulation (1) shall not bear the CE marking and regulation 9 shall not apply.

(7) Where an authorisation pursuant to sub-regulations (1) and (3) is valid, the Technical Regulations Division shall with respect to such products take all corrective and restrictive actions provided for under the Market Surveillance and Compliance of Products Regulations and these regulations. The Technical Regulations Division shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

(8) The use of the authorisation procedure established in sub-regulations (1) and (2) shall not affect the application of the relevant conformity assessment procedures stipulated in regulation 15.

22D. (1) Without prejudice to regulation 17, products which are in conformity with the standards or common specifications or parts thereof referred to in these regulations, or parts thereof, shall be presumed to be in conformity with the applicable essential health and safety requirements established in Schedule II which are covered by those standards, common specifications or parts thereof.

S.L. 427.105.

Presumption of conformity based on harmonised standards and common specifications.

(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 referred to in sub-regulation (1).

(3) By way of derogation from regulation 22A(3), unless there is sufficient reason to believe that the products 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 products 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 applicable essential health and safety requirements established in Schedule II after the expiry or deactivation of the internal market emergency mode.

(4) When the Technical Regulations Division considers that a standard or common specification as referred to in sub-regulation (1) does not entirely satisfy the relevant essential health and safety requirements specified in Schedule I, it shall inform the Commission by submitting a detailed explanation thereof.

Prioritisation of
market surveillance
activities and
mutual assistance
among authorities.

22E. The Technical Regulations Division 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."
