Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 21,508, 19 ta' Settembru, 2025
Taqsima B

L.N. 202 of 2025

PRODUCT SAFETY ACT
(CAP. 427)

Radio Equipment (Amendment) Regulations, 2025

IN EXERCISE of the powers conferred by articles 38, 39 and 40 of the Product Safety Act, the Minister responsible for consumer affairs, on the advice of the Director General (Technical Regulations), has made the following regulations:-

Citation, scope and commencement. S.L. 427.41.

1. (1) The title of these regulations is the Radio Equipment (Amendment) Regulations, 2025 and these regulations shall be read and construed as one with the Radio Equipment Regulations, hereinafter referred to as the "principal regulations".

(2) The scope of these regulations is to:

(a) implement the requisites of Commission Delegated Regulation (EU) 2019/320 of 12 December 2018 supplementing of Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3)(g) of that Directive in order to ensure caller location in emergency communications from mobile devices;

(b) implement the requisites of Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in points (d), (e) and (f) of Article 3(3) of the said Directive;

(c) implement the requisites of Commission Delegated Regulation (EU) 2023/2444 of 20 July 2023 amending Delegated Regulation (EU) 2022/30 as regards the date of application of the essential requirements for radio equipment and correcting that Regulation;

(d) transpose the provisions of 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; and

(e) transpose the provisions of 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.

(3) Regulation 3 shall be deemed to have come into force on 1st August 2025:

Provided that regulations 2 and 9 shall come into force on 30th May 2026.

Amends regulation 3 of the principal regulations.

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

(a) immediately after the definition "conformity assessment body" thereof 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;";

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

""internal market emergency mode" shall have the same meaning assigned to it by point (3) of Article 3 of Regulation (EU) 2024/2747;";

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

"notified bodies" means conformity assessment bodies designated by a Member State to assess the conformity of certain products before being placed on the market;";

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

""Regulation (EU) 2016/679 means Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);

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);".

Amends regulation 4 of the principal regulations.

3. Immediately after sub-regulation (6) of regulation 4 of the principal regulations there shall be added the following new sub-regulations:

"(7) The essential requirement established in sub-regulation (3)(d) shall apply to any radio equipment which may communicate itself over the internet, whether it communicates directly or via any other equipment, also referred as internet-connected radio equipment.

(8) The essential requirement established in sub-regulation (3)(e), shall apply to any of the following radio equipment:

(a) internet-connected radio equipment, other than the equipment referred to in paragraphs (b), (c) or (d);

(b) radio equipment designed or intended exclusively for childcare;

(c) radio equipment regulated by the Safety of Toys Regulations; S.L. 427.40.

(d) radio equipment designed or intended, whether exclusively or not exclusively, to be worn on, strapped to, or hung from any of the following:

(i) any part of the human body, including the head, neck, trunk, arms, hands,

legs and feet;

(ii) any clothing, including headwear, hand wear and footwear, which is worn by human beings:

Provided that such radio equipment is capable of processing, in accordance with the meaning of Article 4(2) of Regulation (EU) 2016/679:

(a) personal data, as defined in Article 4(1) of Regulation (EU) 2016/679, or;

(b) traffic data or location data, as defined in regulation 2(2) of the Processing of Personal Data (Electronic Communications Sector) Regulations.

S.L. 586.01.

(9) The essential requirement established in regulation 4(3)(f) shall apply to any internet connected radio equipment, if that equipment enables the holder or user to transfer money, monetary value or virtual currency as defined in article 310E(d) of the Criminal Code.

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(10) By way of derogation from sub-regulations (7), (8) and (9), the essential requirements established in sub-regulation (3)(d), (e) and (f) shall not apply to radio equipment to which either of the following Union harmonisation legislation also applies:

(a) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; and

(b) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

(11) By way of derogation from sub-regulations (8) and (9), the essential requirements established in sub-regulation (3)(e) and (f) shall not apply to radio equipment to which any of the following Union harmonisation legislation also applies:

(a) Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91;

(b) Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166; and

(c) the Motor Vehicles (Interoperability of Electronic Road Tolls Systems) Regulations. S.L. 65.29.

(12) The essential requirements established in sub-regulation (3)(g) shall apply to hand-held mobile phones with features similar to those of a computer in terms of capability to treat and store data.

(13) Compliance with sub-regulation (9) shall be ensured through technical solutions for the reception and processing of Wi-Fi data, data from Global Navigation Satellite Systems compatible and interoperable with at least the Galileo system referred to Regulation (EU) 2021/696 of the European Parliament and of the Council of 28 April 2021 establishing the Union Space Programme and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013 and (EU) No 377/2014 and Decision No 541/2014/EU and for the making available of that data for

transmission in emergency communications.".

Amends regulation 8 of the principal regulations.

4. Sub-regulation (2) of regulation 8 of the principal regulations shall be deleted.

Amends regulation 29 of the principal regulations.

5. Sub-regulations (2) and (4) of regulation 29 of the principal regulations shall be deleted.

Amends regulation 30 of the principal regulations.

6. In sub-regulation (1) of regulation 30 of the principal regulations, the words "It shall immediately inform the European Commission and the other Member States accordingly." shall be deleted.

Amends regulation 36 of the principal regulations.

7. Sub-regulations (2), (4)(b) and (6) of regulation 36 of the principal regulations shall be deleted.

Amends regulation 37 of the principal regulations.

8. Sub-regulation (3) of regulation 37 of the principal regulations shall be deleted.

Adds new regulations to the principal regulations.

9. Immediately after regulation 39 of the principal regulations there shall be added the following new regulations:

"Application of emergency procedures.

39A. (1) The TRD shall ensure that the measures taken in accordance with this regulation and with regulations 39B to 39D apply only during the activation of internal market emergency procedures pursuant to Article 28 of Regulation (EU) 2024/2747 with respect to radio equipment mentioned in 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 the measures taken in accordance with this regulation and with regulations 39B to 39D apply only to radio 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 the measures taken in accordance with this regulation and with regulations 39B to 39D apply only during the internal market emergency mode that may be activated in accordance with article 18 of Regulation (EU) 2024/2747:

Provided that regulation 39C(7) shall apply during the internal market emergency mode and after its expiry or deactivation.

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

39B. (1) The provisions of this regulation apply to radio equipment referred to in regulation 39A(1) which is subject to the conformity assessment procedures referred to in regulation 17 and which require the mandatory involvement of a notified body.

(2) The notified bodies shall as a matter of priority, process all applications for a conformity assessment of radio equipment referred to in sub-regulation (1), irrespective of whether those applications have been submitted before or after the activation of the emergency procedures pursuant to regulation 39A.

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

(4) The notified bodies shall take all reasonable measures to increase their testing capacities for radio 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.

39C. (1) By way of derogation from regulation 17, the TRD may authorise, on a duly justified request from an economic operator, the placing on the market in Malta of specific radio equipment referred to in regulation 39A(1) for which the conformity assessment procedures referred to in regulation 17 which require the mandatory involvement of a notified body have not been carried out:

Provided that compliance with all the relevant essential requirements established in regulation 4 has been determined in accordance with the procedures referred to in the said authorisation.

(2) The radio equipment subject to the authorisation referred to in sub-regulation (1) shall include the information that they are placed on the market as a crisis-relevant good.

(3) The information referred to in sub-regulation (2), as well as any labelling shall be clear, intelligible and which may be easily understood by consumers and other end-users, and where relevant, shall be written in the English or Maltese language.

(4) The authorisation granted by the TRD shall be valid only in Malta and on the territories of any other Member State whose competent authorities have recognised the validity of that authorisation before the adoption of the derogation referred to in sub-regulation (1).

(5) Manufacturers of radio equipment subject to the authorisation procedure referred to in sub-regulation (1) shall declare their sole responsibility that the radio equipment concerned complies with all the relevant essential requirements established in regulation 4 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 establish the conditions and requirements under which the radio equipment may be placed on the market. Such authorisations shall establish at least the following:

(a) a description of the procedures, by means of which compliance with the relevant essential requirements established in regulation 4 was successfully demonstrated;

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

(c) an end date of validity of the authorisation, which may 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 radio equipment concerned;

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

(7) By way of derogation from regulations 9, 19 and 20, radio equipment for which an authorisation has been granted in accordance with sub-regulation (1) shall not contain the CE marking and regulation 9 shall not apply.

(8) Where an authorisation pursuant to sub-regulations (1), (2) and (4) is valid, the MSD shall with regard to such radio equipment, take all corrective and restrictive actions provided for in accordance with the Market Surveillance and Compliance of Products Regulations.

S.L. 427.105.

(9) The use of the authorisation procedure provided in sub-regulations (1), (2) (4) and (6) shall not affect the application of the relevant conformity assessment procedures provided in regulation 17.

Presumption of conformity based on standards and common specifications.

39D. (1) Without prejudice to regulation 16, radio equipment which is in conformity with the standards or common specifications referred to in Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council shall be presumed to be in conformity with the relevant essential requirements provided for in regulation 4 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 standards, or the common specifications referred to in sub-regulation (1).

(3) By way of derogation from regulation 39A(3), unless there is sufficient reason to believe that the radio equipment covered by the standards or common specifications referred to in sub-regulation (1) presents a risk to the health or safety of persons, the radio 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 relevant essential requirements provided for in regulation 4 after the expiry or deactivation of the internal market emergency mode.".

Deletes regulation 40 of the principal regulations.

10. Regulation 40 of the principal regulations shall be deleted.

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