

SUBSIDIARY LEGISLATION 427.34

LOW VOLTAGE ELECTRICAL EQUIPMENT REGULATIONS

20th April, 2016*

LEGAL NOTICE 97 of 2016.

1. (1) The title of these regulations is the Low Voltage Electrical Equipment Regulations. Citation and commencement.

(2) These regulations transpose Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on low voltage electrical equipment and repealing Directive 2006/95/EC.

(3) These regulations lay down requirements for products referred to in regulation 2(1) and made available on the market, and shall apply as from the 20th April, 2016.

2. (1) These regulations shall apply to electrical equipment, designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current. Scope.

(2) These regulations shall not apply to the electrical equipment and phenomena listed in Schedule II.

3. In these regulations, unless the context otherwise requires: Interpretation.
"authorised representative" means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

"the Authority" means the Malta Competition and Consumer Affairs Authority established by article 3 of the Malta Competition and Consumer Affairs Authority Act; Cap. 510.

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

"conformity assessment" means the process demonstrating whether the safety objectives referred to in regulation 5 and set out in Schedule I relating to electrical equipment have been fulfilled;

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

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

"harmonised standard" means harmonised standard as defined in

*See regulation 1(3).

paragraph (c) of point 1 of Article 2, "a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation" of Regulation EU. No 1025/2012 of the European Parliament and of the Council of 25 October 2012;

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

"making available on the market" means any supply of electrical equipment for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means any natural or legal person who manufactures electrical equipment or has electrical equipment designed or manufactured, and markets that equipment under his name or trade mark;

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

"placing on the market" means the first making available of electrical equipment on the Union market;

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

"technical specification" means a document that prescribes technical requirements to be fulfilled by an electrical equipment;

"TRD" means the Technical Regulations Division within the Authority;

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

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

Transitional provisions.

4. Any electrical equipment in conformity with Directive 2006/95/EC and placed on the market before 20 April 2016 will not be impeded from being made available on the market.

Conformity with safety criteria.

5. (1) Electrical equipment as referred to in regulation 2(1) may be made available on the market only if, having been constructed in accordance with good engineering practice in safety matters in force, it does not endanger the health and safety of persons and domestic animals, or property, when properly installed and maintained and used in applications for which it was made.

(2) The principal elements of the safety objectives referred to in sub-regulation (1) are listed in Schedule I.

(3) All appropriate measures shall be taken to ensure that if electrical equipment is of such a nature as to comply with the provisions referred to in sub-regulation (1), subject to the conditions laid down in regulations 6(1), 6(2), 6(3) and 6(4), the free movement thereof in Malta shall not be impeded for reasons of

safety.

(4) In relation to electrical equipment, stricter safety requirements than those referred to in sub-regulation (1) shall not be imposed by electricity supply bodies for connection to the grid, or for the supply of electricity to users of electrical equipment.

6. (1) When placing their electrical equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the safety objectives referred to in regulation 5 and set out in Schedule I.

Obligations of manufacturers.

(2) Manufacturers shall draw up the technical documentation referred to in Schedule III and carry out the conformity assessment procedure referred to in Schedule III or have it carried out.

(3) Where compliance of electrical equipment with the safety objectives referred to in regulation 5 and set out in Schedule I has been demonstrated by the conformity assessment procedure referred to in sub-regulation (1), manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

(4) Manufacturers shall keep the technical documentation referred to in Schedule III and the EU declaration of conformity for 10 years after the electrical equipment has been placed on the market.

(5) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with these regulations. Changes in product design or characteristics and changes in the harmonised standards referred to in regulation 12(1), the international or national standards referred to in regulations 12(2) and 12(3), or in other technical specifications by reference to which conformity of electrical equipment is declared shall be adequately taken into account.

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

(7) Manufacturers shall ensure that electrical equipment which they have placed on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the electrical equipment does not allow it, that the required information is provided on its packaging or in a document accompanying the electrical equipment.

(8) Manufacturers shall indicate on the electrical equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the electrical equipment. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and the MSD.

(9) Manufacturers shall ensure that the electrical equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the TRD. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

(10) Manufacturers who consider or have reason to believe that electrical equipment which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that electrical equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the electrical equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the electrical equipment available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(11) Manufacturers shall, further to a reasoned request from the TRD, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the electrical equipment with these regulations, in either Maltese or English. They shall cooperate with the TRD, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have placed on the market.

Authorised
representatives.

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

(2) The obligations laid down in regulation 6(1) and the obligation to draw up technical documentation referred to in regulation 6(2) shall not form part of the authorised representative's mandate.

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

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the electrical equipment has been placed on the market;
- (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of electrical equipment; and
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by electrical equipment covered by the authorised representative's mandate.

Obligations of
importers.

8. (1) Importers shall place only compliant electrical equipment on the market.

(2) Before placing electrical equipment on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the electrical equipment bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in regulations 6(7) and 6(8).

(3) Where an importer considers or has reason to believe that electrical equipment is not in conformity with the safety objectives referred to in regulation 5 and set out in Schedule I, he/she shall not place the electrical equipment on the market until it has been brought into conformity. Furthermore, where the electrical equipment presents a risk, the importer shall inform the manufacturer and the MSD to that effect.

(4) Importers shall indicate on the electrical equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the electrical equipment. The contact details shall be in a language easily understood by end-users and the MSD.

(5) Importers shall ensure that the electrical equipment is accompanied by instructions and safety information in either Maltese or English.

(6) Importers shall ensure that, while electrical equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the safety objectives referred to in regulation 5 and set out in Schedule I.

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

(8) Importers who consider or have reason to believe that electrical equipment which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that electrical equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the electrical equipment presents a risk, importers shall immediately inform the TRD, giving details, in particular, of the non-compliance and of any corrective measures taken.

(9) Importers shall, for 10 years after the electrical equipment has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the MSD and ensure that the technical documentation can be made available to those authorities, upon request.

(10) Importers shall, further to a reasoned request from the TRD, provide it with all the information and documentation in paper or

electronic form necessary to demonstrate the conformity of electrical equipment in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have placed on the market.

Obligations of distributors.

9. (1) When making electrical equipment available on the market distributors shall act with due care in relation to the requirements of these regulations.

(2) Before making electrical equipment available on the market distributors shall verify that the electrical equipment bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the electrical equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in regulations 6(7) and 6(8) and regulation 8(4) respectively.

(3) Where a distributor considers or has reason to believe that electrical equipment is not in conformity with the safety objectives referred to in regulation 5 and set out in Schedule I, he shall not make the electrical equipment available on the market until it has been brought into conformity. Furthermore, where the electrical equipment presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the MSD.

(4) Distributors shall ensure that, while electrical equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the safety objectives referred to in regulation 5 and set out in Schedule I.

(5) Distributors who consider or have reason to believe that electrical equipment which they have made available on the market is not in conformity with these regulations shall make sure that the corrective measures necessary to bring that equipment into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the electrical equipment presents a risk, distributors shall immediately inform the MSD, giving details, in particular, of the non-compliance and of any corrective measures taken.

(6) Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of electrical equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have made available on the market.

Application of obligations of manufacturers to distributors and importers.

10. (1) Cases in which obligations of manufacturers apply to importers and distributors.

(2) An importer or distributor shall be considered a manufacturer for the purposes of these regulations and he shall be subject to the obligations of the manufacturer under regulation 6, where he places electrical equipment on the market under his name

or trade mark or modifies electrical equipment already placed on the market in such a way that compliance with these regulations may be affected.

11. (1) Economic operators shall, on request, identify the following to the MSD:

Economic operators.

- (a) who has supplied them with electrical equipment; and
- (b) to whom they have supplied electrical equipment.

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

12. (1) Electrical equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the safety objectives referred to in regulation 5 and set out in Schedule I covered by those standards or parts thereof.

Presumption of conformity.

(2) Where harmonised standards referred to in sub-regulation (1) have not been drawn up and published, for the purposes of making available on the market or free movement as referred to in regulations 5(1) and 5(3) respectively, electrical equipment which complies with the safety provisions of the international standards set out by the International Electrotechnical Commission (IEC) in respect of which the publication procedure laid down in sub-regulation (1) and in this sub-regulation has been applied, shall also be regarded as complying with the safety objectives referred to in regulation 5 and set out in Schedule I.

(3) Where harmonised standards referred to in sub-regulation (1) have not been drawn up and published and international standards referred to in regulation 13 have not been published, for the purpose of making available on the market or free movement as referred to in regulation 5, electrical equipment manufactured in accordance with the safety provisions of the standards in force in the Member State of manufacture, if it ensures a safety level equivalent to that required in their own territory, shall also be regarded as complying with the safety objectives referred to in regulation 5 and set out in Schedule I.

13. (1) The EU declaration of conformity shall state that the fulfilment of the safety objectives referred to in regulation 5 and set out in Schedule I has been demonstrated.

EU declaration of conformity.

(2) The EU declaration of conformity shall have the model structure set out in Schedule IV, shall contain the elements specified in Module A as set out in Schedule III and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the electrical equipment is placed or made available on the market.

(3) Where electrical equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU

declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

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

CE marking.

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

(2) The CE marking shall be affixed visibly, legibly and indelibly to the electrical equipment or to its data plate. Where that is not possible or not warranted on account of the nature of the electrical equipment, it shall be affixed to the packaging and to the accompanying documents.

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

(4) Improper use of the CE marking shall subject the relevant economic operator/s to the measures described in regulation 19.

Market surveillance, control of electrical equipment entering the market.

15. Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to electrical equipment.

Procedure for dealing with electrical equipment presenting a risk at national level.

16. (1) Where the MSD has sufficient reason to believe that electrical equipment covered by these regulations presents a risk to the health or safety of persons or domestic animals, or to property, the relevant economic operators shall cooperate as necessary for the MSD to carry out an evaluation in relation to the electrical equipment concerned covering all relevant requirements laid down in these regulations.

(2) Where, in the course of the evaluation referred to in sub-regulation (1), the MSD finds that the electrical equipment does not comply with the requirements laid down in these regulations, they shall without delay require the relevant economic operator shall without delay take all appropriate corrective actions to bring the electrical equipment into compliance with those requirements, to withdraw the electrical equipment from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

(3) Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in regulation 16(3).

(4) Where the MSD considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the economic operator to take.

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

(6) Where the relevant economic operator does not take adequate corrective action within the period referred to in the second sub-regulation (2), the MSD shall take all appropriate provisional measures to prohibit or restrict the electrical equipment's being made available on the national market, to withdraw the electrical equipment from that market or to recall it.

(7) The MSD shall inform the Commission and the other Member States, without delay, of those measures.

(8) The information referred to in the sub-regulation (7) shall include all available details, in particular the data necessary for the identification of the non-compliant electrical equipment, the origin of the electrical equipment, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the MSD shall indicate whether the non-compliance is due to either of the following:

- (a) failure of the electrical equipment to meet the safety objectives referred to in regulation 5 and set out in Schedule I relating to the health or safety of persons or domestic animals, or to property; or
- (b) shortcomings in the harmonised standards referred to in regulation 12(1) or in the international or national standards referred to in regulations 12(2) and 12(3) conferring a presumption of conformity.

17. (1) Where, having carried out an evaluation under regulation 16(1), the TRD finds that although electrical equipment is in compliance with these regulations, it presents a risk to the health or safety of persons, or to domestic animals or to property the relevant economic operator shall take all appropriate measures to ensure that the electrical equipment concerned, when placed on the market, no longer presents that risk, to withdraw the electrical equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Compliant electrical equipment which presents a risk.

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

(3) The MSD shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the electrical equipment concerned, the origin and the supply chain of the electrical equipment, the nature of the risk involved and the nature and duration of the national measures taken.

18. (1) Without prejudice to regulation 16, where the MSD makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

Formal non-compliance.

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of regulation

14.

- (b) the CE marking has not been affixed;
- (c) the EU declaration of conformity has not been drawn up;
- (d) the EU declaration of conformity has not been drawn up correctly;
- (e) technical documentation is either not available or not complete;
- (f) the information referred to in regulation 6(8) or regulation 8(4) is absent, false or incomplete;
- (g) any other administrative requirement provided for in regulation 6 or regulation 8 is not fulfilled.

(2) Where the non-compliance referred to in sub-regulation (1) persists, the MSD shall take all appropriate measures to restrict or prohibit the electrical equipment being made available on the market or ensure that it is recalled or withdrawn from the market.

Penalties.

19. Economic operators failing to comply with the requirements of these regulations are subject to the provisions of article 26 of the Product Safety Act.

Cap. 427.

SCHEDULE I

PRINCIPAL ELEMENTS OF THE SAFETY OBJECTIVES FOR ELECTRICAL EQUIPMENT DESIGNED FOR USE WITHIN CERTAIN VOLTAGE LIMITS

1. General conditions

- (a) The essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the equipment, or, if this is not possible, on an accompanying document.
- (b) The electrical equipment, together with its component parts should be made in such a way as to ensure that it can be safely and properly assembled and connected.
- (c) The electrical equipment should be designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 is assured providing that the equipment is used in applications for which it was made and is adequately maintained.

2. Protection against hazards arising from electrical equipment

Measures of a technical nature should be described in accordance with point 1, in order to ensure that:

- (a) persons and domestic animals are adequately protected against danger of physical injury or other harm which might be caused by electrical contact direct or indirect;
- (b) temperatures, arcs or radiation which would cause a danger, are not produced;
- (c) persons, domestic animals and property are adequately protected against non-electrical dangers caused by electrical equipment which are revealed by experience;
- (d) the insulation is suitable for foreseeable conditions.

3. Protection against hazards which may be caused by external influences on the electrical equipment

Technical measures are to be laid down in accordance with point 1, in order to ensure that the electrical equipment:

- (a) meets the expected mechanical requirements in such a way that persons, domestic appliances and property are not endangered;
 - (b) is resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered;
 - (c) does not endanger persons, domestic animals and property in foreseeable conditions of overload.
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SCHEDULE II

EQUIPMENT AND PHENOMENA OUTSIDE THE SCOPE
OF THESE REGULATIONS

- Electrical equipment for use in an explosive atmosphere.
- Electrical equipment for radiology and medical purposes.
- Electrical parts for goods and passenger lifts.
- Electricity meters.
- Plugs and socket outlets for domestic use.
- Electric fence controllers.
- Radio-electrical interference.
- Specialized electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate.
- Custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

SCHEDULE III

MODULE A

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the electrical equipment concerned satisfy the requirements of these regulations that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the electrical equipment's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the electrical equipment. The technical documentation shall, where applicable, contain at least the following elements:

- (a) a general description of the electrical equipment;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the electrical equipment;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or international or national standards referred to in regulation 12 and, where those harmonised standards or international or national standards have not been applied, descriptions of the solutions adopted to meet the safety objectives of these regulations, including a list of other relevant technical specifications applied. In the event of

partly applied harmonised standards or international or national standards referred to in regulation 12, the technical documentation shall specify the parts which have been applied;

- (e) results of design calculations made, examinations carried out, etc.; and
- (f) test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured electrical equipment with the technical documentation referred to in point 2 and with the requirements of these regulations that apply to it.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual electrical equipment that satisfies the applicable requirements of these regulations.

4.2. The manufacturer shall draw up a written EU declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national market surveillance authorities for 10 years after the electrical equipment has been placed on the market. The EU declaration of conformity shall identify the electrical equipment for which it has been drawn up.

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

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

SCHEDULE IV

EU DECLARATION OF CONFORMITY (No. XXXX) (*)

1. Product model/product (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of electrical equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the electrical equipment):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. Additional information:
Signed for and on behalf of:

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

(place and date of issue):

(name, function) (signature):.
