

## National Electrical Safety Board's regulations in English – 2016:1

**THIS IS NOT LEGAL/JUDICIAL TEXT.** This document contains a rough translation of National Electrical Safety Board's regulations. Its contents is not legal text and it should only be used for readers who wish to get a general understanding of the contents in the Swedish regulations concerning electrical safety and electromagnetic compatibility. The texts are not necessarily comprehensive, complete, accurate or up-to-date. For legal text - please use the link below.

**Section of legislation:** Products

**Number:** ELSÄK-FS 2016:1

**Amendments per 2017-01-01:** No amendments

**Title:** The National Electrical Safety Board's regulations on electrical equipment

**Legal titel:** Elsäkerhetsverkets föreskrifter (2016:1) om elektrisk utrustning

**Link to regulations:** <http://www.elsakerhetsverket.se/om-oss/lag-och-ratt/gallande-regler/Elsakerhetsverkets-foreskrifter-listade-i-nummerordning/elsak-fs-20161/>

**Implement directive:** Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast).

**Link to directive:** <http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage/>

## Chapter 1 Introductory provisions

### Scope

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.

These regulations shall not apply to the following equipment and phenomena.

- 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 household and similar purposes
- Electric fence controllers
- Radio-electrical interference
- Specialised 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.

### Definitions

2 § The definitions in the Swedish Ordinance (1993:1068) on electrical equipment shall have the same meanings in the application of these regulations.

In these regulations terms are defined as follows:

<i>making available on the market</i>	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,
<i>placing on the market</i>	the first making available of electrical equipment on the Union market,
<i>manufacturer</i>	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,
<i>authorised representative</i>	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,
<i>importer</i>	any natural or legal person established within the Union who places electrical equipment from a third country on the Union market,
<i>distributor</i>	any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes electrical equipment available on the market,
<i>economic operator</i>	the manufacturer, the authorised representative, the importer and the distributor,
<i>technical specification</i>	a document that prescribes technical requirements to be fulfilled by the electrical equipment,
<i>harmonised standard</i>	harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012,
<i>conformity assessment</i>	the process demonstrating whether the safety objectives referred to in Chapter 2 1 § relating to electrical equipment have been fulfilled,
<i>recall</i>	any measure aimed at achieving the return of electrical equipment that has already been made available to the end-user,
<i>withdrawal</i>	any measure aimed at preventing electrical equipment in the supply chain from being made available on the market,

<i>Union harmonisation legislation</i>	Union legislation harmonising the conditions for the marketing of products,
<i>CE marking</i>	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.

## **Chapter 2 Making available on the market and general safety objectives**

**1 §** The prerequisites for making electrical equipment available on the market and the essential requirements are contained in 3-7 and 9 §§ of the Swedish Ordinance (1993:1068) on electrical equipment or regulations superseding it.

## **Chapter 3 Conformity of the electrical equipment**

### **Presumption of conformity of equipment**

**1 §** Provisions concerning the presumption of conformity on the basis of harmonised standards are contained in 8 § of the Swedish Ordinance (1993:1068) on electrical equipment or regulations superseding it.

**2 §** Where harmonised standards referred to in Chapter 3 1 § have not been drawn up and published, the electrical equipment which complies with the safety provisions of the international standards set out by the International Electrotechnical Commission (IEC) shall be regarded as complying with the safety objectives where this confers presumption according to the second paragraph and unless otherwise is demonstrated.

Such standards shall only confer presumption if they have been published in accordance with Article 13 points 2 and 3 of Directive 2014/35/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment.

**3 §** Where standards referred to in Chapter 3 1-2 §§ have not been drawn up and published, the electrical equipment which complies with the safety provisions of standards applicable in the manufacturer's Member State shall be regarded as complying with the safety objectives if the equipment ensures a safety level equivalent to that required in their own territory.

#### **EU declaration of conformity**

**4 §** The EU declaration of conformity shall state that the fulfilment of the safety objectives referred to in Chapter 2 1 § has been demonstrated.

**5 §** The EU declaration of conformity shall have the model structure set out in Annex 2, shall contain the elements specified in Module A in Annex 1 and shall be continuously updated.

The EU declaration of conformity shall be written in an official language of the EU and translated into Swedish or English.

**6 §** 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.

**7 §** 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**

**8 §** Before the electrical equipment is placed on the market, CE marking shall be affixed.

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.

The CE marking shall be in accordance with Article 30 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, etc.

## **Chapter 4 Obligations of economic operators**

### **Obligations of manufacturers**

**1 §** When placing his electrical equipment on the market, a manufacturer shall ensure that it has been designed and manufactured in accordance with the safety objectives referred to in 4-7 §§ of the Swedish Ordinance (1993:1068) on electrical equipment or regulations superseding it.

**2 §** The manufacturer shall draw up the technical documentation referred to in Annex 1 and carry out the conformity assessment procedure referred to in Annex 1.

Where compliance of electrical equipment with the safety objectives referred to in 4-7 §§ of the Swedish Ordinance (1993:1068) on electrical equipment or regulations superseding it has been demonstrated by the conformity assessment procedure referred to in the first paragraph, the manufacturer shall draw up an EU declaration of conformity and affix the CE marking.

**3 §** The manufacturer shall keep the technical documentation referred to in Annex 1 and the EU declaration of conformity for 10 years after the electrical equipment has been placed on the market.

**4 §** The manufacturer shall ensure that procedures are in place for series production to remain in conformity with the requirements. Changes in product design or characteristics and changes in the harmonised standards referred to in Chapter 3 1 §, the international or national standards referred to in Chapter 3 2-3 §§ or in other technical specifications by reference to which conformity of electrical equipment is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by electrical equipment, the manufacturer 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.

**5 §** The manufacturer shall ensure that electrical equipment placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the equipment does not allow

it, that the required information is provided on the packaging or in a document accompanying the equipment.

**6 §** The manufacturer shall indicate, on the electrical equipment, his name, registered trade name or registered trade mark and the postal address at which he can be contacted or, where that is not possible, on the 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.

**7 §** The manufacturer shall ensure that the electrical equipment is accompanied by instructions and safety information in Swedish. Such instructions and safety information, as well as any marking, shall be clear, understandable and intelligible.

**8 §** A manufacturer who considers or has reason to believe that electrical equipment which he has 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, the manufacturer shall immediately inform the National Electrical Safety Board, giving details, in particular, of the non-compliance and of any corrective measures taken.

#### **Authorised representative**

**9 §** A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Chapter 4 1 § and the obligation to draw up technical documentation referred to in Chapter 4 2 § shall not form part of the authorised representative's mandate.

**10 §** 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:

- 1 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,
- 2 provide a competent national authority with all the information and documentation necessary to demonstrate the conformity of the electrical equipment, and

- 3 cooperate with the competent national authorities on any action taken to eliminate the risks posed by the electrical equipment covered by the authorised representative's mandate.

### **Obligations of importers**

**11 §** An importer shall place only compliant electrical equipment on the market.

**12 §** Before placing electrical equipment on the market, the importer shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. The importer 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 Chapter 4 5-6 §§.

**13 §** Where an importer considers or has reason to believe that electrical equipment is not in conformity with the safety objectives set out in Chapter 2 1 §, the importer 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 National Electrical Safety Board to that effect.

**14 §** The importer shall indicate, on the electrical equipment, his name, registered trade name or registered trade mark and the postal address at which he can be contacted or, where that is not possible, on the packaging or in a document accompanying the electrical equipment. The contact details shall be provided in Swedish.

**15 §** The importer shall ensure that the electrical equipment is accompanied by instructions and safety information in Swedish.

**16 §** The importer shall ensure that, while electrical equipment is under his responsibility, the storage or transport conditions do not jeopardise compliance of the equipment with the safety objectives set out in Chapter 2 1 §.

**17 §** When deemed appropriate with regard to the risks presented by electrical equipment, the importer 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.

**18 §** An importer who considers or has reason to believe that electrical equipment which he has 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 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.

**19 §** The importer 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 market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

#### **Obligations of distributors**

**20 §** When making electrical equipment available on the market a distributor shall act with due care in relation to the requirements of these regulations.

**21 §** 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 Swedish, and that the manufacturer and the importer have complied with the requirements set out in Chapter 4 5-6 and 14 §§ respectively.

Where a distributor considers or has reason to believe that the electrical equipment is not in conformity with the safety objectives set out in Chapter 2 1 §, the distributor shall not make the 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 market surveillance authorities.

**22 §** The distributor shall ensure that, while electrical equipment is under his responsibility, the storage or transport conditions do not jeopardise compliance of the equipment with the safety objectives set out in Chapter 2 1 §.

**23 §** 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 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.

**Othe provisions concerning the obligations of economic operators**

**24 §** An importer or distributor shall be considered a manufacturer for the purposes of these regulations and shall be subject to the obligations of the manufacturer under Chapter 4 in these circumstances

- where he places electrical equipment on the market under his name,
- where he places electrical equipment on the market under his trade mark, or
- where he modifies equipment already placed on the market in such a way that compliance with these regulations may be affected.

**25 §** Provisions concerning the National Electrical Safety Board's right, upon request, to obtain the information and the documents necessary for supervision are contained in Chapter 12 2 § of the Swedish Electricity Act (1997:857) or regulations superseding it.

**26 §** An economic operator shall be able to provide information about

- a. economic operators which have supplied electrical equipment to it, and
- b. economic operators to which it has supplied electrical equipment.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the electrical equipment and for 10 years after they have supplied the electrical equipment.

## Chapter 5 Compensation and supervision fees

**1 §** Provisions concerning the National Electrical Safety Board's right to obtain one or more copies for supervision from economic operators are contained in Chapter 12 5 § of the Swedish Electricity Act (1997:857) or regulations superseding it.

The economic operator from which the National Electrical Safety Board obtains electrical equipment shall receive compensation equal to the purchase price including VAT plus transport costs.

**2 §** If the electrical equipment does not meet the safety objectives in Chapter 2 1 §, the economic operator providing the electrical equipment shall reimburse the National Electrical Safety Board for its costs in purchasing and testing the equipment.

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## Entry into force and transitional arrangements

These regulations enter into force on 20 April 2016.

1. These regulations repeal the National Electrical Safety Board's regulations (2000:1) on certain electrical equipment and general implementation advice.
2. Electrical equipment placed on the market before 20 April 2016 in accordance with the National Electrical Safety Board's regulations (2000:1) on certain electrical equipment and general implementation advice may be made available on the market even after these regulations enter into force.
3. The provisions in Chapter 4 4 § second paragraph, Chapter 4 8 § and Chapter 4 17-19, 23 and 26 §§ shall apply from 1 May 2016.

## **Annex 1: Module A - Internal production control**

### **1 Internal production control**

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 satisfies 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, wherever 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 Chapter 3 2-3 §§ 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 Chapter 3 2-3 §§, the technical documentation shall specify the parts which have been applied. results of design calculations made, examinations carried out, etc.,
- 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.

## Annex 2: Model structure of EU declaration of conformity

### EU declaration of conformity (No Xxxx)<sup>1</sup>

- 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:

(place and date of issue)

(name, function) (signature)

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<sup>1</sup>It is optional for the manufacturer to assign a number to the declaration of conformity.