



EUROPEAN POWER SUPPLIES MANUFACTURERS' ASSOCIATION
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CE MARKING GUIDANCE FOR POWER SUPPLIES

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The European Power Supplies Manufacturers' Association was established in 1995 to represent the European power supply industry.

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1 Introduction

This document was prepared by the Technical Committee (TC) of the EPSMA to find a common understanding and interpretation of CE-marking among EPSMA companies and their customers.

Its aim is to have a common understanding of the application of several European directives relevant to Power Supplies.

However, it is the responsibility of the manufacturer to determine which and in which way, directives are applicable to their power supply units (PSUs).

2 List of relevant Directives

N°	Title	Common abbreviation	Issue date	Date of transposition
Most relevant directives for PSUs				
2001/9 5/EC	General Product Safety Directive	GPSD	12/03/2001	15/01/2004
2014/35/EU	Low Voltage Directive (electrical equipment designed for use within certain voltage limits)	LVD	26/02/2014	19/04/2016
2014/30/EU	Electromagnetic Compatibility Directive	EMC	26/02/2014	19/04/2016
2011/65/EU	Restriction of the use of certain Hazardous Substances in Electrical and Electronic Equipment	RoHS II	08/06/2011	02/01/2013
2012/19/EU	Waste Electrical and Electronic Equipment	WEEE II	04/07/2012	14/02/2014
Other directives referring to particular applications				
93/42/EEC	Medical Devices	MDD	14/06/1993	01/01/1995
2014/53/EU	Radio Equipment	RED	16/04/2014	12/06/2016
2014/34/EU	Explosive Atmospheres	ATEX	26/02/2014	19/04/2016

Directives and other documents related to (i.e. list of standards) are available on EU website (EURLEX). <http://eur-lex.europa.eu/advanced-search-form.html?action=update&qid=1396451801676>

2.1 Low Voltage Directive (LVD)

The new LVD was adopted by the European Council on 24th of February 2014. It is mandatory from 20th of April 2016. It applies to electrical apparatus with an AC input or output voltage rating of 50V to 1000V or DC input or output voltage rating from 75V to 1500V.

2.2 EMC Directive

The new EMC directive was adopted by the European Council on 24th of February 2014. It is mandatory from 20th of April 2016.

For the purpose of this Directive a "component" is defined as any item which is used in the composition of an apparatus and which is not itself an apparatus with a direct function intended for the final user.

Therefore, a detailed analysis of the intended use of power supply is necessary to check the application of the EMC Directive (see 4.2)

2.3 RoHS II Directive

The new RoHS Directive (RoHS II) was mandatory from 2nd of January 2013. Unless products are specifically listed as one of the exemptions, the RoHS II directive applies to every manufacturer of electrical and electronic equipment. Products already bearing the CE Mark must also satisfy the RoHS II directive.

Refer to http://www.epsma.org/decision_tree_RoHS_2013_May_07.pdf available on the EPSMA Website for the application of RoHS II Directive.

2.4 WEEE II Directive

The new WEEE Directive was adopted by the European Council on 4th of July 2012. It was mandatory from 14th of February 2014 and replaces previous Directive 2002/96.

WEEE II Directive requires the application of the "bin" symbol on the unit. No CE marking is required.

Refer to http://www.epsma.org/decision_tree_WEEE_2013_May_13%20web%20180613.pdf available on the EPSMA Website for the application of WEEE II directive.

2.5 Medical Directive (MDD)

A medical device is an apparatus with the purpose of diagnosis, prevention, monitoring, treatment or alleviation of injuries or diseases or an apparatus with the purpose of investigation, replacement or modification of the anatomy or of a physiological process or the control of conception.

A power supply is only a part of such an apparatus and is considered as an accessory without medical function. Therefore, no CE marking and no Declaration of Conformity is required.

2.6 ATEX Directive

Power supplies are typically utilized in ATEX Zone 2 environments. For ATEX Zone 2 a notified body is not required. A unit can be self-certified when the required knowledge is available. However, it is recommended that the power supply is tested by a third party. The ATEX directive requires a CE Mark on the unit together with the ATEX classification code, and issue of a Declaration of Conformity. The Declaration of Conformity must be shipped with the product.

The ATEX directive differentiates between products and components. A power supply is regarded as a product and needs to fulfil all requirements for the product category.

2.7 RED Directive

New Radio Equipment Directive (RED) 2014/53/EU replaces Radio and telecommunications terminal equipment (R&TTE) 1999/5/EC.

All radio devices operating up to 3000 GHz included are in the scope of the directive.

RED directive refers to LVD Directive 2014/35/EU, (but with no voltage limit applying); and to EMC directive 2014/30/EU.

3 Types of PSU

3.1 Stand-alone power supplies

These are intended for free-standing operation in laboratories, workshops and other areas. As such they are accessible to the final user. Typical examples include bench units, laboratory power supplies, free standing and wall mounted products, desk-top or direct plug-in types, and battery chargers.

3.2 Built-in power supply units

Component Power Supplies (CPS)

Power Supplies, also known as OEM, Modular or Sub Unit Power Supplies, are designed, produced and intended to be "professionally installed" into a final dedicated product. "Professionally installed" requires that the installer is technically competent and able to satisfy the requirements of the Directives applicable to the final product. CPS are not intended for free-standing applications and are not intended to be accessible to the final user. Typical examples of such power supplies include open card, open frame, plug-in card power supplies, enclosed and encapsulated units or power supply modules.

Component power supplies or DIN RAIL power supplies intended to be installed by an end-user are considered as apparatus and therefore fall in the EMC directive scope.

4 Applicable directives / Type of PSU

Type of PSU	Applicable directives								Comment
	GPSD	LVD	EMC	RoHS	MDD	RED	WEEE	ATEX	
Stand-alone	X	X	X	X	(1)	(5)	(2)	(3)	See 4.1
Built-in CPS	X	X	(4)	X	(1)	(5)	(2)	(3)	See 4.2

- (1) Power supplies are considered to be an accessory without medical function (See 2.5)
- (2) Refer to decision tree for the application of WEEE Directive
- (3) Power supplies are considered to be products (See 2.6)
- (4) Refer to flowchart http://www.epsma.org/CE%20Marking_Flowchart_Issue%2020180523.pdf for the application of EMC directive
- (5) Referring to LVD and EMC directives

4.1 Applicable directives for Stand-alone PSUs

- Since January 1997 it has been mandatory to CE mark under the LVD.
- For Power Supplies intended for free-standing operation, the EMC Directive is mandatory and CE marking is required.
- RoHS II became mandatory for all devices from January 2013 and requires the application of CE mark.

4.2 Applicable directives for Built-in PSUs

The following directives apply to PSUs placed on the market as separate individual units to be integrated in electrical equipment:

- Since January 1997 it has been mandatory to CE mark under the LVD.
- Any built-in power supply (CPS) installed by an end-user should satisfy the essential requirements of the EMC directive subject to its particular precautions of installation (e.g. power line filters are installed at the main power input line of the apparatus). However, CE Marking is not mandatory for each application. See flowchart: http://www.epsma.org/CE%20Marking_Flowchart_Issue%2020180523.pdf for more details.

Therefore, it is the responsibility of the final equipment manufacturer to ensure that the end product complies with the EMC Directive and to CE mark for it if applicable. A CPS is a possible source of electromagnetic interference, but the configuration of the equipment into which it is installed can significantly alter the EMC characteristics that are measured on the CPS. Also, the installer may experience difficulties in ensuring that the final equipment complies with the EMC Directive if the design of the CPS has not taken into account EMC considerations.

The EMC directive does not apply to evaluation kits for R&D tests.

It is not mandatory that demonstration devices satisfy the directive but they need to be marked with an adequate statement regarding non-compliance with the directive.

The EMC directive does not apply if a CPS is built-in to specific product families covered by dedicated directives (i.e. MDD).

- Rohs II became mandatory for all devices from January 2013 and requires the application of the CE mark.

5 List of major harmonized standards

For each directive, a list of harmonized standards is published. The following Table includes major harmonized standards at 2017.

Directive	Harmonized standards	Title	Comments
2014/35/EU (LVD)	EN 60950-1	Information technology equipment - Safety - Part 1: General requirements	Valid up to 19/12/2020 and replaced by EN 62368-1
	EN 62368-1	Audio/video, information and communication technology equipment- Part 1: Safety requirements	Replaces EN 60950-1 from 19/06/2019 (see note 1)
	EN 62477-1	Safety requirements for Power electronic converter systems and equipment- Part 1: General	
	EN 61204-7	Low voltage power supplies, d.c. output- Part 7: Safety requirements	
	EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	
	EN 61010-2-201	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-201: Particular requirements for control equipment	
	EN 61558-2-16	Safety of transformers, reactors, power supply units and similar products for supply voltages up to 1 100 V - Part 2-16: Particular requirements and tests for switch mode power supply units and transformers for switch mode power supply units	
2014/30/EU (EMC)	EN 61000-6-1	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments	
	EN 61000-6-2	Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments	
	EN 61000-6-3	Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments	
	EN 61000-6-4	Electromagnetic compatibility (EMC) - Part 6-4: Generic standards - Emission standard for industrial environments	

Directive	Harmonized standards	Title	Comments
	EN 55032	Electromagnetic compatibility of multimedia equipment - Emission Requirements	Replaced EN 55022 since 05/03/2017
	EN 55011	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	
	EN 61204-3	Low voltage power supplies, d.c. output- Part 3: Electromagnetic compatibility (EMC)	
2011/65/EU (RoHS)	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	
93/42/EEC (MDD)	EN 60601-1	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance	
	EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	
2014/53/EU (RED)			Refers to LVD and EMC directives
2012/19/EU (WEEE)	/	/	No list published
2014/34/EU (ATEX)	EN 60079-0	Explosive atmospheres - Part 0: Equipment - General requirements	
	EN 60079-7	Explosive atmospheres - Part 7: Equipment protection by increased safety "e"	
	EN 60079-15	Explosive atmospheres - Part 15: Equipment protection by type of protection "n"	

Note 1. Date postponed to 20/12/2020 by CENELEC, still in adoption process by EU commission

The standard considered for CE Mark must be in correlation with the end-application of the power supply.

6 EU Requirements

Since 1994, according to 93/68/EEC (CE marking), for every CE-marked product, the supplier shall have a Declaration of Conformity and prepare documentation to prove compliance with applicable standards and directives.

The LVD and EMC directives are some of the directives that have been updated to be aligned with the new legislative Framework (Decision 768/2008/EC, regulation 764/2008, regulation 765/2008). The new measures have been defined to improve:

- Market surveillance rules
- Quality of the conformity assessment
- Meaning of CE marking
- Common legal framework

New requirements are:

- Application on the device (or packaging, or documentation provided with device) of a single point address where the manufacturer (or importer) can be contacted
- Analysis and assessment of the risks must be part of documentation

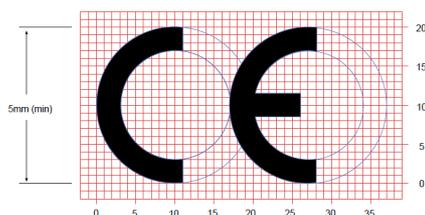
Type of requirements	Applicable directives								Comment
	GPSD	LVD	EMC	RoHS	MDD	RED	WEEE	ATEX	
CE Mark		X	X	X	X (*)	X		X	
EU DoC		X	X	X	X (*)	X		X	
Risk assessment		X	X		X	X		X	
Specific marking					X		"bin" symbol	Explosion protection marking and classification code	Defined by related directives
Address on product		X	X	X	X	X		X	

(*) not required for Built-in PSU (see 2.5)

6.1 CE Mark

According to Article 30 of Regulation (EC) No 765/2008 :

The CE marking shall consist of the initials 'CE' taking the following form:



It can be proportionally reduced and enlarged with a minimum height of 5mm.

A smaller size is accepted by some directives (i.e. RED), provided that it remains visible and legible.

6.2 EU Declaration of Conformity

The EU Declaration of Conformity (DoC) shall have the model structure set out in the Annex of Directives and shall be continuously updated.

It shall be translated into the language or languages required by the Member State in which market the electrical equipment is placed or made available.

A single EU declaration of conformity shall be drawn up in respect of all Union acts.

Minimum Information required on a DoC is:

- A description of the product which is the object of the declaration (all information necessary to identify the product)
- Name and address of the manufacturer
- A statement regarding conformity to EU legislation and referring to the relevant directives
- A list of the relevant harmonized standards (if applicable) or other technical specifications in relation to which conformity is declared
- Reference to notified body and certificate issued (if applicable)
- Place and date of issue
- Name and function of signatory(ies)

According to the ATEX Directive, an EU DoC must be shipped with the product.

6.3 Technical documentation

The documentation prepared by the manufacturer shall make it possible to assess the conformity of the device to the relevant requirements. The documentation package shall include at least:

- An adequate analysis and assessment of the risk(s). (See CENELEC Guide 32 or other applicable method such as EN 31010)
- A description of the apparatus
- Design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc. including relevant explanations
- A list of the harmonized standards or other technical specifications applied either in full or partially
- Results of design calculations made, examinations carried out, etc.
- Test reports
- For MDD only, a description of essential requirements

Technical documentation and an EU DoC should be kept available for 10 years after the apparatus has been placed on the market.

6.4 Address on the product

According to the new regulation, it is mandatory to apply on the device (or when not possible because of the size or physical characteristics of the products, on packaging and/or accompanying documentation) a single point address where the manufacturer (or importer) can be contacted. The address must be a single contact point inside the European Union.

The address on the unit and EU DoC should be the same. An address normally consists of a street and number or post-box and number and the postal code and town. A web address or link to the handbook is not acceptable but may be used as a source of additional information.

Also, in situations where say, a sub-contractor manufactures the product for a company, the prime contractor company address should be on the label and DoC, not the manufacturer.

6.5 Instructions (or manual)

The manufacturer, importer and distributor have the obligation to ensure that the product is accompanied by instructions in a language which can be easily understood by consumers and other end-users as determined by the Member State concerned. It is for each economic operator which makes available the product in a Member State, to ensure that all the required languages are available.

6.6 Responsibilities

6.6.1 Definitions

Manufacturer: any natural or legal person who manufactures electrical equipment or has electrical equipment designed or manufactured, and markets that equipment under their name or trademark.

Authorized representative: any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on their behalf in relation to specified tasks.

Importer: any natural or legal person established within the Union who places apparatus from a third country on the Union market.

Distributor: any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes electrical equipment available on the market.

6.6.2 Obligations

Manufacturers must:

- Be responsible for the conformity assessment procedure
- Draw up the required technical documentation
- Draw up the EU Declaration of conformity
- Provide instructions and safety information with the product
- Satisfy the traceability requirements
- Affix the CE marking

- Ensure that procedures are in place for series production to remain in conformity
- Certify the product and/or the quality system (if required)

In addition, manufacturers must:

- Keep a register of complaints and keep distributors informed
- Identify to market surveillance authorities any operator to whom they have supplied a product
- Take the necessary corrective measures in case of non-conformity to the directives
- Inform the competent national authorities of the Member States in which they made the electrical equipment available in case of risk detection

These obligations apply to importers or distributors who are placing products on the market under their own trademark.

6.6.3 Traceability:

Power supplies which have been placed on the market should satisfy the following traceability requirements:

- EU DoC and technical documentation are kept 10 years after the product has been placed on the market
- A power supply which has been placed on the market should bear a type, batch or serial number or other element allowing its identification on the product. If technically not possible to provide this information on the product, information may be provided on packaging or in documentation accompanied
- Name, registered trace name/mark and single contact point of manufacturer/importer is indicated on the label or packaging or documentation of each product

Sources:

- The 'Blue Guide' on the implementation of EU product rules 2016
Ref. Ares(2016)1614475 - 05/04/2016
- Guide for the EMC Directive 2014/30/EU
Final Draft, 4 May 16
- (EURLEX). <http://eur-lex.europa.eu/advanced-search-form.html?action=update&qid=1396451801676>
- CE marking flowchart [www.epsma.org/CE Marking Flowchart Issue 2 20180523.pdf](http://www.epsma.org/CE%20Marking%20Flowchart%20Issue%2020180523.pdf)

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EPSMA - Secretariat Address
EPSMA Secretariat
20, Little Haseley
Oxfordshire
OX44 7LH
UK

secretariat@epsma.org