eurofins | Electrosuisse Product Testing

The CE Marking – Access to the European Market

The EU dictates the compliance of guidance and a CE marking for many industrial products, so that these products may attain to the market.

The experts of Eurofins Electrosuisse Product Testing AG support you in all project phases,

from the concept phase to the introduction on the market:

- Consulting and education in EU guidelines;
- Project appraisal (short review, position fixing);
- CE-accomplishment of development;
- CE-appraisal of conformity of the products;
- Safety-related tests according to harmonized standards;
- EMC measurements and analysis of compliance;
- Risk analysis (mechanical concepts, protective gear).

Compliance with directives
The CE directive may only be used if all basic safety and health requirements are fulfilled, which are defined in the current guidelines.
The Building technique and appliance determine which guidelines have to be considered.

0201/1403-100e

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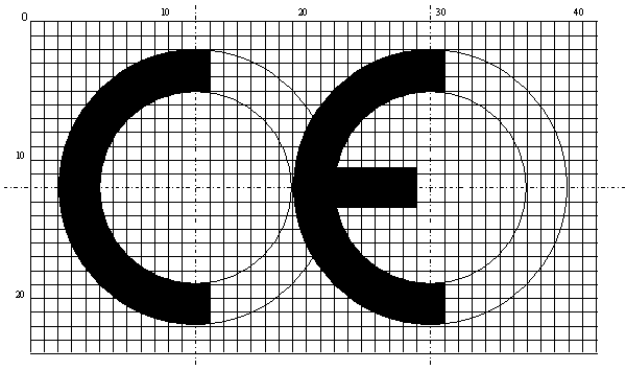
Short information on CE-marking
Selection of directives, which access the appliance for electrical equipment, devices or engines:

2014/35/EU	**Low Voltage Directive** Counts for electrical equipment / components for the use with nominal voltage from 50 to 1000V alternating voltage and 75 to 1500V direct voltage.
2006/42/EC	**Machinery directives** Counts for engines* incl. equipment for extension of functions, as well as parts of it, for safety assembly, chains, ropes, straps and other load-handling-devices and demountable articulated shafts. *) «engine» is defined as the following: The summary of interconnected parts which are added for a certain appliance and from those at least one is moveable and gets moved by a drive mechanism.
93/42/EEC **90/385/EEC** 2007/47/EC	**Directive for Medical Devices / implantable medical devices** Affects systems, which are meant for therapy or relief of human diseases**.**
2014/30/EU	**EMC Directive (Electromagnetic Compatibility)** Affects devices / components and engines which can cause electro-magnetic error or whose business can get damaged by these errors.
2014/34/EU	**ATEX Directive: Devices and Protection System for the Usage in Potentially Explosive Atmospheres** Affects devices / components and systems which are used in explosive areas.

CE Marking
The CE mark of conformity is composed of the letters «CE» with the following type face:



In case of reduction or enlargement of the CE mark, the proportions must be kept within the pictured pattern.

Definitions

Manufacturer
Every natural or juridical person who constructed or built the product under one's own name or put in circulation. The manufacturer is responsible for the compliance with the requirements of the guidelines.

Technical Documentations (technical files):
Include all documents, which allocate that the product agrees with the requirements of the guidelines. This includes information concerning the design, manufacturing, commissioning and operation of the products.

The technical documentations typically include:

- A general description of the product
- The plan of the product
- Drawings of the design and manufacturing, diagrams, circuits
- Owner's manual
- List of standards that will be applied and/or measures to ensure compliance with the essential requirements
- All audit reports, information on the quality management, descriptions of the products, which are used for the production and processes, etc.

These documents must be kept from the manufacturer until at least 10 years after the product's placing on the market.

EC Declaration of Conformity
In the declaration of conformity, the manufacturer or his authorized representative established in the EU, notes that the product fulfills all basic security and health requirements of the above mentioned guidelines.

An EC Conformity Declaration shall contain in essence:
- Product identification
- Name and address of the manufacturer
- Name and signature of the responsible person for the fulfillment of the directive's requirements
- List of the standards that will be applied/or other measures for compliance with the requirements of the directive

The exact information required in the respective directive is set out in the annex (p. 5 & 6).

EC Type Examination
This tool can only be used with products directly subordinated to the machinery directive. Assembly groups, which are destined for the installation in a machine or for the assembly with other parts of machinery, will receive no CE marking and need an EC type examination instead of the EC declaration of conformity. See Machinery Directive 2006/42/CE Art. 2 break g)

Conformity Assessment
Depending on the product and its application, either the manufacturer or his authorized representative or a nominated or responsible body will accomplish the conformity evaluation. That means it will be checked whether the essential safety and health requirements are fulfilled.

Notified Body
Independent, accredited testing and/or certification authority are designated by the corresponding EC commission. Eurofins Electrosuisse Product Testing AG operates as a Notified Body no. 1258 testing laboratory and certification body for the concerns of the ATEX Directive 2014/34/EU and EMC Directive 2014/34/EU.

Competent Body
Independent, accredited testing and/or certification authority that has to meet the same requirements as a notified body, but is not designated by the EC commission.
Evidence which the manufacturer can provide himself, can also be run by a competent body.

Accreditation
The laboratories of Eurofins Electrosuisse Product Testing AG are accredited according to ISO 17025, the certification body for Products according to ISO 17065. The accreditation is carried out by the Swiss Accreditation Body SAS. Our certifications are internationally recognized by the well-known CCA and CB schemes.

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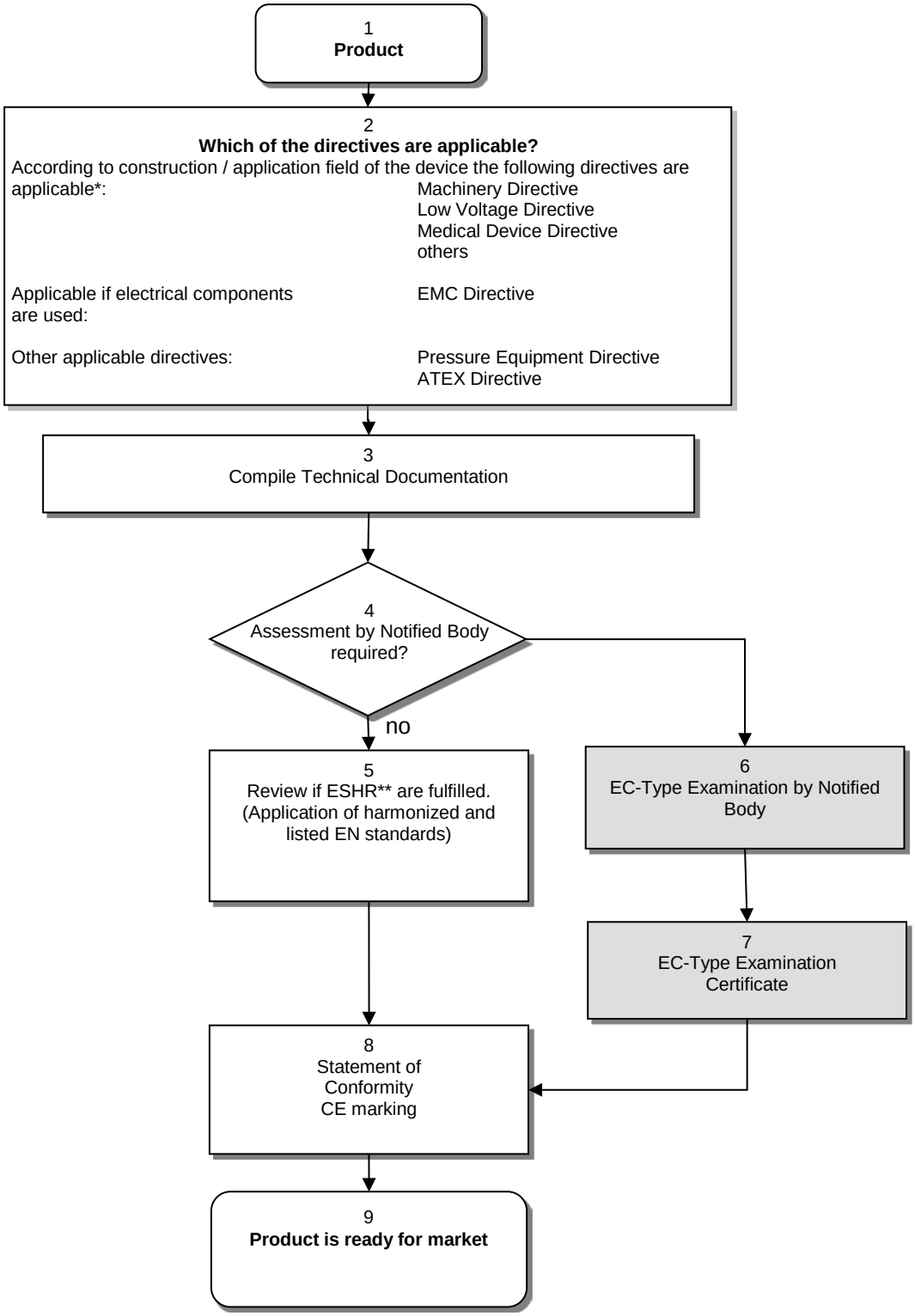
CE Marking Procedure



*) Machinery and Low Voltage Directive are to apply exclusively (for determination see Machinery Directive Cl. 1. k) If the product is used as a device for purposes of health for human beings the Medical Device Directive may replace the Machinery Directive.
**) Essential Health and Safety Requirements

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EG/EC/CE

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY
DÉCLARATION DE CONFORMITÉ

Wir
We
Nous

_____
(Name des Anbieters) (supplier's name) (nom du fournisseur)

_____
(Anschrift) (address) (adresse)

erklären in alleiniger Verantwortung, dass das Produkt
declare under our sole responsibility that the product
déclarons sous notre seule responsabilité que le produit

_____
_____
_____
(Bezeichnung Typ oder Modell, Los-, Chargen- oder Seriennummer, möglichst Herkunft und Stückzahl)
(name, type or model, lot, batch or serial number, possibly sources and numbers of items)
(nom, type ou modèle, no de lot, d'échantillon ou de série, éventuellement sources et nombre d'éxemplaires)

auf das sich diese Erklärung bezieht, mit den folgenden Normen übereinstimmt.
to which this declaration relates is in conformity with the following standards.
auquel se réfère cette déclaration est conforme aux normes.

_____
(Titel und/oder Nummer sowie Ausgabedatum der Norm(en) oder der anderen normativen Dokument(e))
(title and/or number and date of issue of the standard(s) or other normative document(s))
(titre et/ou no et date de publication de la (des) norme(s) ou autre(s) document(s) normatif(s))

Gemäss den Bestimmungen der Richtlinien;
following the provisions of Directives
conformément aux dispositions de Directives
(falls zutreffend) (if applicable) (le cas échéant)

_____
_____
_____

_____

(Ort und Datum der Ausfertigung)	(Name, Unterschrift oder gleichwertige Kennzeichnung des Befugten)
(Place and date of issue)	(name and signature or equivalent marking of authorized person)
(Lieu et date)	(nom et signature du signataire autorisé)