

CE marking machinery and related products.

Based on the Machinery Regulation (EU) 2023/1230 and
related products

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CE marking machinery and related products 1^e print.

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Preface:

In the 1^e edition of this book about the new Regulation for machinery and related products (EU) 2023/1230 we are putting the word “NEW” for changed information in relation to the previous Machinery Directive 2006/42/EG.

The Directive is changed into a Regulation because the Regulation is from the moment it is published integrated into the local law, a Directive must be locally integrated in the local laws during the Transitional period.

On 29 of June 2023 the Regulation Machinery and related products (EU) 2023/1230 is published and mentioned in the official Journal L165. After 20 days (29 July 2023) the Regulation (EU) 2023/1230 will be Law in alle member states of the EU. The Transitional period of 42 months is in place until the Directive 2006/42/EU will be repealed. On 20 January 2027 this Regulation (EU) 2023/1230 must be applied.

In this book you will not find a copy of the Regulation for machinery and related products! We describe in this book the things you must do creating a machinery and related products or partly completed machinery. I hope you enjoy this 1^e edition as much as the previous book.

This book is written to help machine manufacturers (designers) to comply with the applicable Regulation/Directives published by the EU.

The common mistake that standards are the “law” and the Regulations/Directives “could be used” is explained.

The Regulations/Directives can be downloaded free of charge from the EU site, because they are the law, the law is free accessible for everyone. (See chapter Links)

The standards are copyright protected and must be bought from the local standardization institutes.

Where text fragments from the (harmonised)standards or Regulations/Directives are used for explanation purposes, they are placed in *Italic*.

To make sure you have the presumption of conformity with the **Essential Health and Safety Requirements (EHSR)** from the Regulations/Directives using the harmonised standards you must buy the (harmonised)standards and make sure you know the content of the Regulations/Directives and (harmonised)standards.

The main difference between the Directive and the Regulation is that in the Regulation several rules given in the harmonised standards are integrated in the Regulation. That means they are law now, instead of pieces of information you may follow. These changes can be found in Annex III the EHSR.

The author.

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1 Introduction to CE marking

What is the meaning of the CE marking of machinery products?

The meaning of the CE marking can be divided into two parts.

For the user it means that the machinery and related products which bears the CE mark complies with the relevant Regulation/Directives and can be used in a safe way.

The other part of the CE marking makes it possible to move/sell this machinery and related products in the EU without extra requirements from the countries to which this machinery and related products are transported.

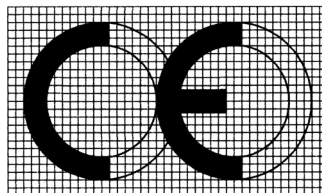
http://europa.eu/index_en.htm

Site with basic information about the European Union.

In principle we are talking about machinery products which bear the CE mark and are accompanied by a declaration of conformity or integration and a manual on paper or digital information where you can find the digital information. Or partly completed machinery which may NOT bear the CE mark but are accompanied by a copy of the fulfilled Essential Health and Safety Requirements (Annex III) of the Machinery products Regulation and related products, a declaration of incorporation and a manual on paper or digital.

Graphical representation of the CE mark.

See for details Directive 93/68/EEG



2 Manufacturer/designer

Definition of the manufacturer from the Machinery Regulation and related products.

NEW article 3

'manufacturer' means any natural or legal person who:

(a) manufactures products within the scope of this Regulation or who has those products designed or manufactured, and markets those products under its name or trademark, or

(b) manufactures products within the scope of this Regulation, and puts those products into service for his own use;

The designer knows all the ins and outs of the design he or she has created. That's the reason the designer is the responsible person to for fill the legal requirements of the applicable Regulations/Directives.

The situation could occur that the designer and the manufacturer are different persons. In this case a contract will be issued in which is agreed who is responsible for the legal requirements and puts the CE mark on the machinery and related products.

In the Regulations/Directives the designer is called the manufacturer. For the sake of compatibility, the same is done in this book. So, we call the "**designer**", "**manufacturer**".

The manufacturer must decide which Regulations/Directives are applicable for the designed machinery and related products. The applicable harmonized standards are also chosen by the manufacturer.

3 Directives/Regulations

We mostly talk about the machinery products Regulation. At the moment this book was written there are 37 Regulations/Directives available.

The Regulations start with; (EU) Nr./Year

The Directives start with; Year/Nr./EU (EG, EC or EEC)

Accessibility:

Directive (EU) 2016/2102 Accessibility of websites and mobile applications of public sector bodies.

Chemicals:

Regulation (EC) No 1907/2006 Chemical substances (REACH)

Directive 2014/28/EU Explosives for civil uses

Directive 2013/29/EU Pyrotechnic articles

Conformity assessment and management systems:

Regulation (EC) No 765/2008 New legislative framework (NLF)

Construction:

Regulation (EU) No 305/2011 Construction products (CPD/CPR)

Consumer and workers protection:

Regulation (EC) No 1223/2009 Cosmetic products

Directive 2001/95/EC General product safety

Regulation (EU) 2016/425 Personal Protective Equipment

Directive 2009/48/EC Toy Safety

Energy efficiency:

Directive 2009/125/EC Eco design and labelling

Regulation (EU) 2017/1369 Framework Directives

Electric and electronic engineering:

Directive 2014/30/EU Electromagnetic Compatibility (EMC)

Directive 2014/34/EU Equipment for Explosive Atmosphere (ATEX)

Directive 2014/35/EU Low Voltage (LVD)

Directive 2014/53/EU Radio Equipment (RED)

Directive 2011/65/EU Restriction of the use of certain hazardous substances (ROHS)

Healthcare engineering:

Regulation (EU) 2017/746 In vitro diagnostic medical devices

Regulation (EU) 2017/745 Medical devices

Directive 90/385/EEC Active implantable medical devices

Directive 98/79/EC In vitro diagnostic medical devices

Directive 93/42/EEC Medical devices

Measuring technology:

Directive 2014/32/EU Measuring instruments (MID)

Directive 2014/31/EU Non-automatic weighing instruments (NAWI)

Mechanical engineering and means of transport:

Regulation (EU) 2016/424 Cableway installations

Directive 2014/34/EU Equipment for explosive atmosphere (ATEX)

Regulation (EU) 2016/426 Gas appliances

Directive 2009/128/EC Inspection of pesticide application equipment

Directive 2014/33/EU Lifts

Directive 2006/42/EC Machinery (MD)

Directive 2014/68/EU Pressure equipment (PED)

Directive (EU) 2016/797 Interoperability of rail system

Directive 2013/53/EU Recreational craft
Directive 2014/29/EU Simple pressure vessels (SPVD)
Regulation (EU) 2019/945 Unmanned aircraft systems (UAS)

Services:

Directive 97/67/EC Postal services

Sustainability:

Directive 94/62/EC Packaging and packaging waste

<http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/>

On this site you can find all the Regulations/Directives mentioned here.

You first choose the languages and then in the next screen you click on the Regulation/Directive name, the site will guide you to the next screen, which gives you detailed info. It gives you also the opportunity to download the Regulation/Directive and the official journal (OJ) in which the harmonised standards are mentioned.

Regulation

When a Regulation is published, after 20 days, it is automatically in all the EU countries the law.

Directive

When a Directive is published there is always a time in which the EU countries are allowed to integrate the Directive into their own law system.

4 Things you must do as manufacturer.

Open a technical file. (Annex IV) (Chapter 5)

Design a Machinery or partly completed machinery.
(Chapter 6)

Describe the limits of your design. (Chapter 7)

Identify each existing hazards. (Chapter 8)

Perform a risk analysis. (Chapter 9)

Try to reduce the risk with a technical/design
measure.

Go back to the risk analysis.

Design a safety system. (Chapter 9)

Determine the PLr (the required Performance Level).
(Chapter 9)

Describe what the function is of the designed safety system
(SRS). (Chapter 10)

Based on the PLr design a single or a dual channel safety
system. (Chapter 11)

Check the B_{10} value, $MTTF_D$ calculation of the used
components.

When there is a residual risk (which you can't reduce with a
technical or design measure). Mark it in the user manual.
(Chapter 12)

When an emergency stop can contribute to the safety of your design, design an emergency stop function. (Chapter 13)

Put all the results of your actions in the technical file. (Chapter 5)

Make sure you comply with the Essential Health and Safety requirements from Annex III.

Don't forget to ask your customer if he wants the manual on paper or digital and in which languages, he wants it. Let him sign a document for his choose. (Chapter 14)

Artificial Intelligence (Chapter 15)

Significant changes to a machinery (Chapter 16)

User manual (Chapter 17)

Intended use and reasonably foreseeable misuse (Chapter 18)

Maintenance/Service manual (Chapter 19)

Declaration of conformance. (Annex V), (Chapter 20)

Declaration of incorporation (Annex V), (Chapter 20)

Assembly instructions for partly completed machinery (Annex XI), (Chapter 21)