DGUV Test
Prüf- und Zertifizierungssystem der
Deutschen Gesetzlichen Unfallversicherung

07

DGUV Test Information

Last updated: 08/2023

Declaration of conformity and CE marking

1 What is CE marking?

In Europe, products falling within the scope of EU legislation must bear the CE marking. The abbreviation CE stands for “Conformité Européenne”, i.e. “European Conformity”. By affixing the CE marking to a product, the manufacturer[1] (e.g. the producer) confirms its compliance with the EU requirements for ensuring the protection of health, safety and the environment. A conformity assessment procedure must be performed before the CE marking is affixed to the product. The majority of EU directives and regulations require the manufacturer to perform the conformity assessment procedure under his own responsibility.
The same applies to the tests required for this purpose. Exceptions provide for a notified body to be involved in the conformity assessment procedure. CE marking is not comparable with voluntary test marks requiring the involvement of an independent body. A detailed comparison between CE marking and voluntary test marks can be found in DGUV Test Information 03 and in the DGUV Test CE marking and test marks (in German available only) informational video.

CE marking

2 Who is responsible?

A manufacturer in the sense of the EU legislation and the German Product Safety Act ProdSG 2021) is any natural or legal person making a product available on the Single Market for the first time, whether in return for payment or free of charge, as part of a business activity. In particular, manufacturers who produce or develop a product themselves or have it produced or developed by others are considered to be manufacturers. Importers or distributors who import a product from a third country are also included under this heading.

The manufacturer is responsible for ensuring that a product is not placed on the European Single Market unless it satisfies the requirements of the relevant EU Directive or Regulation and does not endanger the safety and health of persons when used as intended or in a foreseeable manner. Where a product is not covered by a specific item of EU legislation, it may be made available on the market only if it does not endanger the safety and health of persons when used as intended or in a foreseeable manner. A list of requirements to be met can be found in Section 3 (2) of the ProdSG 2021.

1 Where used below, the term “manufacturer” refers to an economic operator in the form of a designer, producer, authorised representative or importer, whether a natural or legal person (see Chapter R2, Obligations of economic operators, Decision 768/2008/EC).

3 How do I find the right Directive or Regulation concerning my product?

The manufacturer first checks, under his own responsibility, what EU legislation applies to his product. The EU legislation, together with further information such as amendments and, where applicable, guidelines for application, is published on the website of the European Commission. Each item of EU legislation has a specific scope. Readers can generally determine quickly from careful study of the first articles whether or not the EU legislation concerned is applicable. Should no EU legislation specific to the product apply, the CE marking must not be applied to it.

During considering of applicability, it must be noted that other EU legislation applies, besides that requiring CE marking. This includes the REACH Regulation, legislation concerning food contact materials, the Ecodesign Regulation and many other items of legislation, according to the product class.

Note

Companies can find a general overview of EU legislation that may be applicable on the Access2Markets website. This EU database is an interactive online service and is available free of charge. Companies can use it to find information on import and export conditions and on trade within the EU.

4 How must a conformity assessment be performed?

4.1 Objective of conformity assessment

The manufacturer performs the conformity assessment to demonstrate that his product satisfies the requirements of the legislation applicable to it (see TU Dresden and BAuA 2022, in German available only).

The conformity of a product must be assessed before it is placed on the market. Assessment takes place during both the design and production phases.

Although responsibility lies primarily with the manufacturer during performance of the conformity assessment, some legislation may require the involvement of an independent notified body (the “third party”[2]).

Note

In conjunction with Dresden Technical University (TUD), the German Federal Institute for Occupational Safety and Health (BAuA) has developed PROSUm-Er, an interactive, sustainable teaching concept for proactive product and machine safety for use in university education (in German available only). The tuition material can be viewed online and contains comprehensive information on all aspects of product and machine safety. Topic group C addresses the subject of making available on the market.

2 The manufacturer is referred to as primary party and the market surveillance authorities as secondary with respect to their responsibilities for placing on the market.

4.2 Conformity assessment procedures and modules

The conformity assessment procedures have been linked by the EU harmonization regulations to form a modular system by which conformity assessment is to be applied uniformly.

Conformity assessment can be carried out by means of **seven procedures** (see Article 4 of Decision 768/2008/EC). These are grouped from A to H (ibid., Annex II) in a total of **eight modules**. Figure 1 shows an overview of the procedures and the associated modules. Each procedure consists of either one or two modules. Since the products are subject to a conformity assessment in both the design and manufacturing phases, a conformity assessment procedure comprises both phases (see Section 5.1.2 of the Blue Guide 2022).

Not all procedures and modules are applied in all items of product safety legislation. The legislator selects those that are best suited to the product sector in question. For four of these procedures, type-examination (Module B) is employed in conjunction with a further module. The remaining conformity assessment procedures each consist of one module.

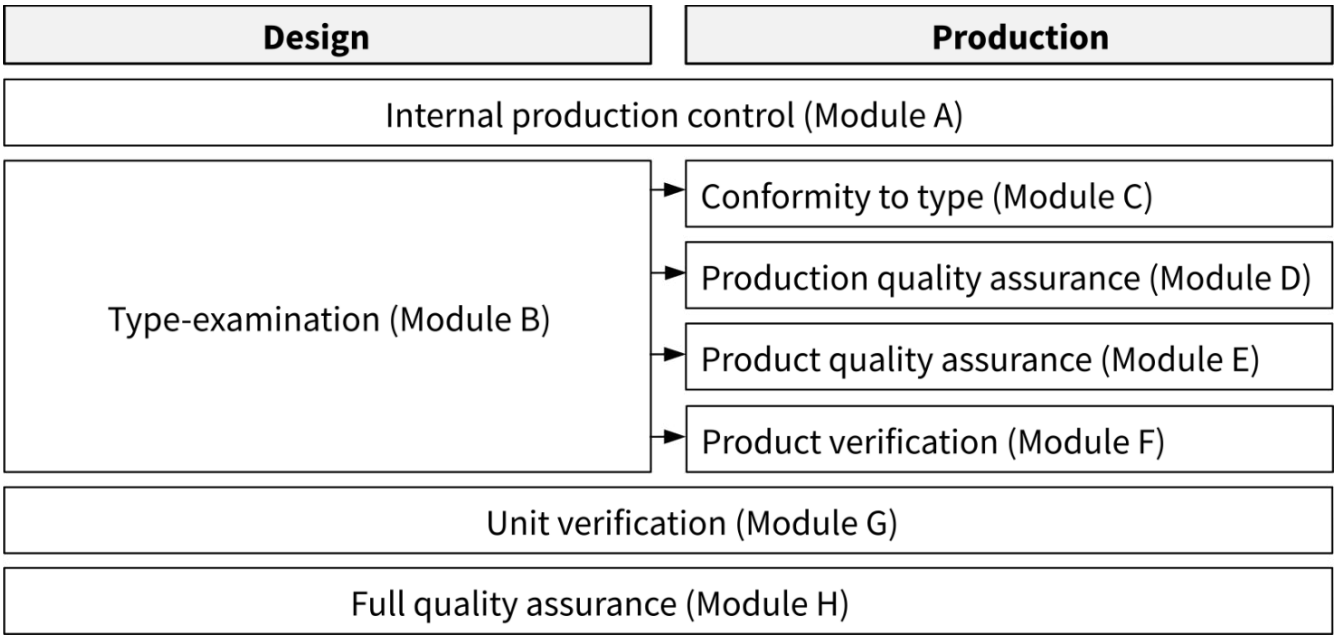

Figure 1: Conformity assessment procedures with associated modules (Translation from German source: PROSUmEr teaching concept for product safety, Topic group C: Making available on the market (TU Dresden and BAuA 2022, Figure 3.1, Licence: CC BY-SA 4.0))

4.3 Conformity assessment procedures for machinery

The Machinery Directive (Machinery Directive 2006/42/EC) makes provision for three procedures for assessing the conformity of machinery:

- Conformity assessment by internal production control (Module A)
- EC type-examination (Module B) in conjunction with internal production control (module A)
- Full Quality Assurance (Module H)

By application (obligatory) of one of the three procedures, the manufacturer demonstrates that the machine complies with the requirements of the Machinery Directive. The procedures themselves are described in Annexes VIII, IX and X of the Machinery Directive 2006/42/EC. This corresponds to the modules of Decision 768/2008/EC.

The procedure to be used by the manufacturer of the machine is determined by whether the machine is classified as dangerous and whether harmonized standards are used for its manufacture (see Article 12 of the Machinery Directive 2006/42/EC).

Machines classified as being particularly dangerous are listed in Annex IV of the Machinery Directive. The EC type-examination procedure (Module B) can be followed for these machines. A notified body must be involved in this procedure. Based on a representative example of the machine (a "type"), the notified body determines whether the provisions of the Machinery Directive are satisfied. The machine may be manufactured in whole, in part, or not in accordance with harmonized standards. The Machinery Directive 2006/42/EC lists the current notified bodies, together with their identification numbers and the tasks assigned to them.

The basic procedure is shown in Figure 2. Further explanations can be found in the PROSUmEr teaching concept on product safety for university education, Topic group C: Making available on the market, Section 3.1.2: Conformity assessment procedures for machinery (TU Dresden and BAuA 2022).

Explanation

Harmonized standards are a particular category of European standards developed by a European standards organization in response to a mandate issued by the European Commission. When a product satisfies the requirements of a harmonized standard, it is presumed to conform with the essential health and safety requirements of the relevant EU product regulations. The Nando database on the European Commission's website contains information on harmonized standards and notified bodies.

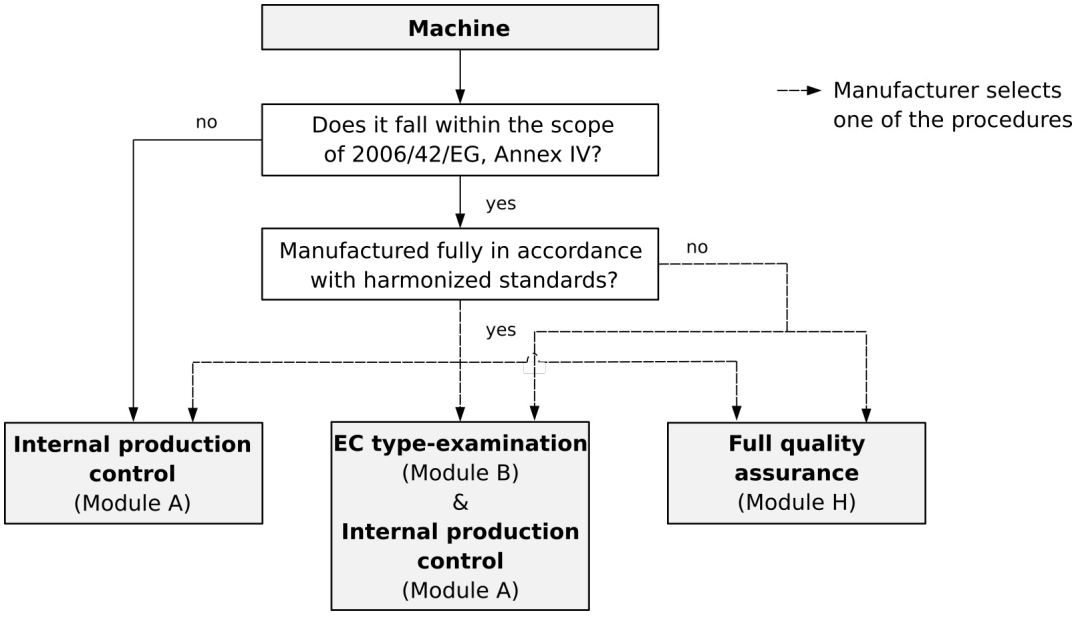

Figure 2: Conformity assessment procedures and modules for machinery (Translation from German source: PROSUmEr teaching concept on product safety for university education, Topic group C: Making available on the market (TU Dresden and BAuA 2022, Figure 3.4, License: CC BY-SA 4.0))

4.4 Conformity assessment procedures for PPE

The choice of conformity assessment procedure depends upon the category of personal protective equipment (PPE). Each item of PPE must be assigned to a risk category in accordance with Annex I of the PPE Regulation (EU) 2016/425. Items of PPE are classified according to the risk against which they are intended to provide protection. Distinction is made according to the following three categories:

- Category I comprises only minor risks.
- Category II comprises risks not listed under Category I or Category III; any item of PPE not falling within Categories I or III is automatically assigned to Category II.
- Category III is limited to risks with potentially severe consequences, such as death or irreversible harm to health.

The conformity assessment procedures to be followed by the manufacturer differ according to the category of PPE (see PPE modules, DGUV Test 2020, in German available only).

Manufacturers of Category I PPE must perform internal production control (Module A) in accordance with Annex IV. The manufacturer uses the technical documentation to demonstrate that the PPE in question satisfies the essential health and safety requirements of the PPE Regulation. The manufacturer issues the EU declaration of conformity and affixes the CE marking to each individual item of PPE.

An EU type-examination (Module B), performed by a notified body, is required for Category II products. The notified body examines the technical design and/or samples of a type. It also verifies that the product complies with the applicable requirements of the PPE Regulation, and certifies this compliance by issuing the EU type-examination certificate. The manufacturing process and the arrangements for monitoring of it must ensure that the manufactured PPE conforms to the type described on the EU type-examination certificate and satisfies the applicable requirements of the PPE Regulation (EU) 2016/425 (Module C). The manufacturer takes all measures required for this purpose.

Due to the high risk against which Category III items of PPE are intended to provide protection, a notified body must be involved in EU type-examination (Module B) of these items and in monitoring.

The manufacturer ensures conformity to the type, either:

a) by means of internal production control involving supervised product checks at irregular intervals (Module C2) in accordance with Annex VII, or
b) by means of quality assurance of the production process (Module D) in accordance with Annex VIII.

5 What does an example of a Declaration of Conformity and a CE marking look like?

In accordance with Section 7 of the ProdSG 2021, the CE marking must be affixed to the product or its type plate in a clearly visible, legible and permanent manner. Should the nature of the product not permit or justify this, the CE marking is affixed to the packaging, or to the accompanying documents where such documents are mandatory. The manufacturer must apply his name and contact address. Where a manufacturer is not established in the European Economic Area, he must instead state the name and contact address of his authorized representative or the importer (Section 6 (1) 2 ProdSG).

Should the notified body have been involved in the production control phase, Section 2 (19) of the ProdSG requires its identification number to be applied after the CE marking. The identification number must be affixed either by the manufacturer or by his authorized representative.

The CE marking can be downloaded here.

A declaration of conformity with reference to an example machine can be found in DGUV Test Information 14.

Further information

- Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC. Official Journal of the European Union: European Parliament.
- Blue Guide 2022. Commission notice: the “Blue Guide” on the implementation of EU product rules 2022. Official Journal of the European Union: European Parliament.
- DGUV Test Information 3: Comparison of the CE Mark and Certification Marks, Webcode p012399
- DGUV Test Information 14: Declaration of Conformity and Declaration of Incorporation as specified in Directive 2006/42/EC, Webcode p022374
- Machinery Directive 2006/42/EC. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast). Official Journal of the European Union: European Parliament.
- Notified bodies for legislation 2006/42/ EC Machinery Directive. European Commission.
- ProdSG 2021. Gesetz über die Bereitstellung von Produkten auf dem Markt Produktsicherheitsgesetz (ProdSG) – Act on Making Products Available on the Market. Bundesgesetzblatt 2021 Part I No 49, issued in Bonn, 30 July 2021: Bundesministerium der Justiz.
- TU Dresden and BAuA. 2022. Lehrkonzept zur Produktsicherheit für die universitäre Ausbildung (PROSUmEr): Themenkomplex C: Bereitstellung auf dem Markt. Wissensbaustein. TU Dresden, commissioned by the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA). In German available only.

Published by:
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Available:
www.dguv.de/publikationen Webcode: p022562

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