

# **“CE” MARK REGULATION**

## **PART ONE**

### **Purpose, Extent, Basis and Definitions**

#### **Purpose**

**ARTICLE 1 – (1)** The purpose of this Regulation is to determine the procedures and principles for placing the (CE) mark on the product and for using this mark.

#### **Extent**

**ARTICLE 2 – (1)** This Regulation is related to the products for which the "CE" mark is stipulated in the relevant technical regulation.

#### **Basis**

**ARTICLE 3 – (1)** This Regulation is prepared in accordance with sub paragraph (a) of the second sub article of article 24 of the Code of Product Safety and Technical Regulations n. 7223 and dated 05.03.2020.

#### **Definitions and abbreviations**

##### **ARTICLE 4 – (1)**

- a) AB: Union European,
- b) Mark “CE”: The mark showing that the product complies with all the relevant rules of the technical legislation that stipulates the placement of the "CE" mark,
- c) Distributor: Real or legal person other than the manufacturer or importer who keeps the product on the market by taking part in the supply chain,
- ç) Manufacturer: Real and legal person who puts the product on the market under his / her own name or trademark by manufacturing or having the product designed or manufactured,
- d) Importer: Real or legal person residing in Turkey who imports the product to the market,
- e) Commission: European Commission,
- f) Module: Each of the ways indicating which conformity assessment processes will be subjected according to the risks of the product in accordance with the relevant technical regulation,
- g) Notified body: Conformity assessment body appointed by Turkey or an authorized institution of an EU member country in line with the principles set out in the relevant legislation and notified to the Commission to carry out conformity assessment activities within the scope of a technical regulation,
- ğ) Pictogram: Figure on the product that illustrates a feature related to the product,
- h) Making available on the market: Provision of the product on the market for distribution, consumption or use through commercial activity, with or without charge,
- i) Placing on the market: the first time a product is placed on the market,
- i) Standard: One of the following technical requirements, which are not compulsory for compliance and that are accepted for repetitive or continuous use by a recognized standardization body;
  - 1) International standards adopted by an international standardization body,

- 2) European standards adopted by a European standardization organization,
- 3) European standards adopted at the request of the Commission for the implementation of EU harmonization legislation,
- 4) National standards adopted by a national standardization body,
- j) Technical regulation: Compulsory legislation, including administrative provisions, which determines the nature of the product, the processing or production methods, or the related terminology, symbol, packaging, marking, labeling or conformity assessment,
- k) Technical specification: Document specifying the technical requirements that a product, process or service must meet,
- l) Conformity assessment: The process that shows whether certain requirements for the product, process, service, system, person or organization have been met,
- m) Conformity assessment body: Organization that carries out conformity assessment activities, including calibration, testing, certification and inspection,
- n) Conformity mark: Mark indicating that the product complies with the relevant technical regulation,
- o) Harmonized standard: The standard adopted at the request of the Commission for the implementation of EU harmonization legislation,
- ö) Authorized institution: Public institution that prepares technical regulations on products, executes or inspects the products,
- p) Authorized representative: Real or legal person resident in Turkey who is assigned in writing by the manufacturer to fulfill some of the manufacturer's obligations under Law No. 7223 and other relevant legislation.

## **PART TWO**

### **Parties' Obligations**

#### **Obligations of the Manufacturer**

**ARTICLE 5 – (1)** The manufacturer, on the condition that other liabilities specified in the relevant technical regulation are reserved shall be obliged to;

- a) issue the technical file required by the relevant technical regulation,
- b) carry out and /or have conformity assessment procedures done,
- c) issue EU Declaration of Conformity and / or other documents attesting the conformity,
- ç) place “CE” mark on the product,
- d) keep the technical file and the EU Declaration of Conformity for the period specified in the relevant technical regulation, or for a period of ten years from the date the product is placed on the market in cases where the time is not specified, and to submit to the authorized institution these documents in Turkish or a language acceptable to the authorized institution

#### **Obligations of the authorized representative**

**ARTICLE 6 – (1)** The authorized representative, on the condition that other liabilities specified in the relevant technical regulation are reserved shall be obliged to;

- a) carry out or have the conformity assessment procedures for the product done if the manufacturer assigns it in writing,
- b) issue the EU Declaration of Conformity or other documents showing the conformity, unless otherwise specified in the relevant technical regulation,

c) place “CE” mark on the product. However, even if the manufacturer has stated it in writing, she cannot draw up the technical file.

(2) In the appointment document, it shall be stated that the authorized representative will keep the documents required by the technical regulation and showing the conformity of the product for the period specified in the technical regulation, or for at least ten years from the date the product is placed on the market in cases where the period is not specified, and will provide it in Turkish or another language that the authorized institution will accept.

### **Obligations of the importer**

**ARTICLE 7 –** (1) The importer, on the condition that other liabilities specified in the relevant technical regulation are reserved shall be obliged to;

- a) confirm that the manufacturer has fulfilled its obligations in article 5,
- b) confirm that the product bears the "CE" mark and that the product is accompanied by the necessary documents,
- c) keep copy of the EU Declaration of Conformity for the period specified in the relevant technical regulation, or for a period of ten years from the date the product is placed on the market in cases where the time is not specified in order to submit the same to the authorized institution in Turkish or a language acceptable to the authorized institution,
- d) submit copy of the technical file which is kept for the period specified in the relevant technical regulation, or for a period of ten years from the date the product is placed on the market in cases where the time is not specified, to the authorized institution in Turkish or a language acceptable to the authorized institution, if requested so.

### **Obligations of the distributor**

**ARTICLE 8 –** (1) The distributor shall take the necessary care while making the product available on the market. The distributor, before placing the product on the market, shall verify that the product bears the "CE" mark and is accompanied by the documents showing its conformity, without prejudice to other obligations specified in the relevant technical regulation. It shall submit all information and documents showing the conformity of the products to the authorized institution upon request of the authorized institution.

### **Situations where the manufacturer's obligations apply to importers and distributors**

**ARTICLE 9 –** (1) Importers and distributors who place a product on the market under their own name or trademark or change a product in a way that affects its compliance with the technical regulation or the general product safety legislation published by the Ministry, are considered as manufacturers within the scope of this Regulation and are obliged to fulfill the obligations of the manufacturer in Article 5.

## **PART THREE**

### **Placement and use of the “CE” mark on the product and the EU Declaration of Conformity**

#### **Placement and use of the “CE” mark on the product**

**ARTICLE 10 –** (1) The general principles for placing and using the CE mark on the product are as follows:

- a) The manufacturer by putting the "CE" mark on the product or ensuring that this mark is put on is deemed to have declared that the conformity of the product with the relevant technical regulation or regulations stipulating the placement of this mark is under his / her responsibility and that the product has been subjected to all necessary conformity assessment procedures.
- b) In case a product is subject to more than one technical regulation requiring the "CE" mark, the "CE" mark on the product constitutes the presumption that all applicable provisions of all relevant technical regulations are fulfilled by the manufacturer. However, in cases where one or more technical regulations give the manufacturer a choice of application during a transitional period, the "CE" mark only indicates compliance with the provisions of the applied technical regulation or regulations.
- c) The mark "CE":
  - 1) shall consist of the letters "CE" in accordance with the form specified in the annex of this regulation (Annex 1 - The shape of the "CE" Mark) and the design of the sign cannot be changed except when it is reduced and enlarged in accordance with the proportions in the drawing.
  - 2) shall be at least 5 mm in size unless otherwise specified in the relevant technical regulation.
  - 3) shall be placed visibly, legibly and indelibly on the products or on the information plate or on the packaging in cases where this is not possible or its permanence cannot be guaranteed due to the nature of the product and on accompanying documents stipulated by the relevant technical regulation.
  - 4) shall be placed before the product is put on the market.
  - 5) shall be placed only by the manufacturer or its authorized representative.
- c) In cases required by the relevant technical regulation, in addition to the "CE" mark, the identity registration number of the notified body in the production control phase shall be also included. The identification number shall be placed by the notified body itself or by the manufacturer or the manufacturer's authorized representative in accordance with the instructions of the organization. In the event that a product is subjected to the evaluation of more than one notified body due to its falling within the scope of different technical regulations, the identity registration numbers of all notified bodies in the production control area shall be placed in addition to the "CE" mark.
- d) Pictograms or other signs that describe a specific risk or use may be placed on the product together with the "CE" mark.
- e) Other signs or descriptions that may mislead third parties about the meaning and shape of the "CE" mark cannot be placed on the product. All other signs can only be placed on the product in a way that does not impair the visibility, readability and meaning of the "CE" mark.
- f) The "CE" mark can only be used on products for which technical regulations stipulate to do so, and cannot be used on other products.
- g) In cases required by the relevant technical regulations, the "CE" mark is placed in a way that can be read by the visually impaired.

### **EU Declaration of Conformity**

**ARTICLE 11** – 1) If the EU Declaration of Conformity is stipulated in the relevant technical regulation, it shall be issued by the manufacturer or authorized representative to inform that the product is in compliance with the requirements of the technical regulation.

(2) Unless otherwise stated in the technical regulation regarding the EU Declaration of Conformity, it shall be prepared in accordance with the content stipulated by the relevant module or modules and in accordance with the annex of this Regulation (Annex – 2 - EU

CONFORMITY DECLARATION EXAMPLE). In cases where it is issued in other languages, a Turkish translation of the declaration shall be included. The statement shall be updated whenever necessary.

(3) In cases where the product is subject to more than one technical regulation requiring an EU Declaration of Conformity, the manufacturer shall demonstrate by issuing a single EU declaration of conformity that these technical regulations fulfill all the rules applicable to the product. The declaration shall include the name, publication date and reference number of these technical regulations.

(4) Once the manufacturer issues and signs the EU declaration of conformity, it is assumed that he shall assume responsibility for compliance with the rules of the relevant technical regulation.

(5) The EU Declaration of Conformity can also be submitted electronically, if the authorized institution agrees.

#### **Other declarations of conformity**

**ARTICLE 12** – (1) If the relevant technical regulation requires a declaration of conformity other than the EU Declaration of Conformity to show the conformity of the product with the requirements of the technical regulation, the declaration of conformity shall be issued in accordance with the procedures and principles specified in the relevant technical regulation.

### **PART FOUR**

#### **Other Provisions**

#### **Equivalence of authorized representatives residing in EU member states**

**ARTICLE 13** – (1) Authorized representatives residing in EU member states shall be considered equivalent to authorized representatives based in Turkey on the basis of reciprocity.

#### **Application**

**ARTICLE 14** – (1) The provisions of this regulation shall be applied together with the technical regulations that require a "CE" mark on the product.

#### **Administrative sanctions**

**ARTICLE 15** – (1) The provisions of Law No. 7223 are applied to those who act against the provisions of this regulation.

#### **Compliance with European Union legislation**

**ARTICLE 16** – (1) This regulation has been prepared within the framework of harmonization with the European Union legislation and is based on the "European Parliament and the Council Regulation No. (EU) 765/2008 dated 09/07/2008 on the Determination of Rules of Market Surveillance and Inspection by Accreditation" and the "European Parliament and Council Decision No. (EU) 768 dated 09/07/2008 on the General Framework Regarding the Placing of Products on the Market".

#### **The abolished regulation and references in the legislation**

**ARTICLE 17** – (1) The "CE" marking regulation put into effect with the Cabinet Decree dated 16/12/2011 and numbered 2011/2588 has been abolished.

(2) In the legislation, the references made to the "CE" marking regulation which has been abolished with the first paragraph are deemed to have been made to this regulation.

**Entrance into effect**

**ARTICLE 18** – (1) This regulation shall enter into force on the date of its publication.

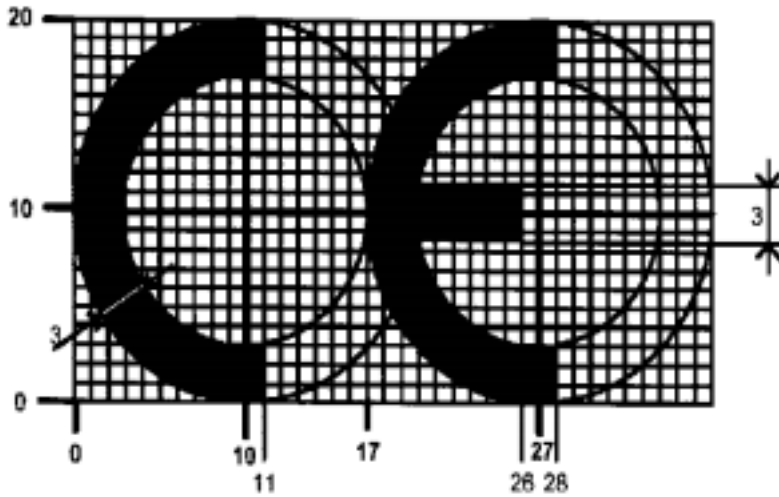
**Execution**

**ARTICLE 19** – (1) The provisions of this regulation are executed by the President.

## ATTACHMENT 1

### THE SHAPING OF "CE" MARK

1. "CE" mark shall consist of letters "CE" in accordance with the following figure and ratio.



2. The proportions in the figure above shall be respected in cases where it is required to be reduced or enlarged.
3. Unless otherwise stated in the relevant technical regulation, the "CE" mark shall be at least 5 mm in size.

## ATTACHMENT 2

### EXAMPLE OF THE EU DECLARATION OF CONFORMITY

1. No ..... ( The number that identifies the product by separating it from others):
2. Name and address of the manufacturer or the authorized representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or the person who installed the product). (name of manufacturer or installer):
4. Subject of the declaration (describe the product for traceability. A photo can be attached where appropriate)
5. The subject of the declaration described above is in accordance with the legislation stated below. (Name of legislation): .....
6. References to relevant harmonized standards used or references to technical specifications for which conformity has been declared:
7. Name and identification number of the notified body involved in and issuing the ..... certificate (to be written with a description of the type of conformity assessment activity)
8. Additional information:

Shall be signed for or on behalf of .....

(Place and date of issuance)

(Name, surname, position/title) (signature)