REGULATION ON THE "CE" MARKING
(Published on Official Gazette and entered into force on 23 February 2012)

CHAPTER I
Objective and Scope, Legal Basis and Definitions

Objective and scope
Article 1- (1) The objective of this Regulation is to specify the conformity assessment modules setting out the methods of affixing the CE marking to the products and the procedures and principles for its use.

(2) Where a technical regulation does not specify a conformity assessment module or EC Declaration of Conformity, although it is in the scope of this Regulation, the provisions of that technical regulation shall be applied.

Legal Basis
Article 2- (1) This Regulation is based on Article 14 of Law No. 4703 on the Preparation and Implementation of the Technical Legislation on Products dated 29/6/2001.

Definitions
Article 3- (1) For the purposes of this Regulation the following definitions shall apply:

a) "EC" shall mean the European Community.

b) "Final product" shall mean the product which does not need any further processing and is ready for direct usage.

c) "CE marking" shall mean the marking which indicates that the product is in conformity with all applicable requirements of the technical regulation providing for affixing of the "CE" marking.

ç) "Distributor" shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

d) "Manufacturer" shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.

e) "Importer" shall mean any natural or legal person established in Turkey who places a product from a foreign market on domestic market.

f) "Commission" shall mean the European Commission.

g) "Module" shall mean each conformity assessment procedures set out in Annex 3 of this Regulation.

ğ) "Notified bodies" shall mean the conformity assessment body established in Turkey, designated by the competent authority in accordance with the Regulation on Conformity Assessment Bodies and Notified Bodies which was put into force by the Decision of the Council of Ministers of 16/12/2011 and No.2011/2621 and relevant

technical legislation to perform conformity assessment procedures laid down in a technical regulation, and notified to the Commission.

h) “Making available on the market” shall mean any supply of a product for distribution, consumption or use on domestic market in the course of a commercial activity, whether in return for payment or free of charge.

ı) “Placing on the market” shall mean the first making available of a product on domestic market.

i) “Pictogram” shall mean any figure on the product illustrating any characteristics of the product.

j) “Standard” shall mean any voluntary document adopted by a national or international standardisation body, aiming to provide an optimum level of order under the existing conditions, laying down -for common and repeated use- one or more of the characteristics, processing or production methods of a product or the related terminology, symbols, packaging, marking, labelling and conformity assessment procedures.

k) “Technical regulation” shall mean any mandatory legislation laying down one or more of the characteristics or processing and production methods of a product or the related terminology, symbols, packaging, marking, labelling and the conformity assessment procedures.

l) “Technical specification” shall mean any document that prescribes technical requirements to be fulfilled by a product, process or service.

m) “Type” a sample which represents the product envisaged to be manufactured.

n) “Conformity assessment” shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.

o) “Conformity assessment body” shall mean a body established in Turkey that performs conformity assessment activities including calibration, testing, certification and inspection.

ö) “Harmonised standard” shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to the Regulation on the Notification of the Technical Legislation and Standards Between Turkey and the European Union published in Official Gazette, dated 3/4/2002 no. 24715.

p) “Harmonized national standard” shall mean a standard adopted by Turkish Standards Institute as a Turkish Standard to transpose a harmonised standard.

r) “Competent authority” shall mean a public body authorized by a law or a regulatory act to draw up or implement legislation concerning to a specific product or a product group or to inspect them.

s) “Authorised representative” shall mean any natural or legal person established in Turkey who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.

CHAPTER II
Obligations of Parties

Obligations of manufacturer
Article 4- (1) Without prejudice to the other obligations laid down in the relevant technical regulation, the manufacturer, as a requirement of the relevant technical regulation, shall draw up technical documentation, carry out conformity assessment procedures or have it carried out, draw up the EC declaration of conformity and affix the CE marking to the product and keep the technical documentation and the EC declaration of conformity for a period specified in the relevant technical regulation and in case that no such period is specified, for 10 years after the product is placed on the market and submit them to the competent authority upon its request.

Obligations of authorised representative
Article 5- (1) Without prejudice to the requirements laid down in the relevant technical regulation and on the condition that it is specified in the written mandate that the manufacturer has handed over his authority to the authorised representative, the authorised representative shall fulfil the obligations of the manufacturer specified in Article 4 except drawing up the technical documentation.

Obligations of importer
Article 6 - (1) Without prejudice to the obligations laid down in the relevant technical regulation, the importer shall verify that the manufacturer has fulfilled all his obligations laid down in Article 4 and the product bears the CE marking and shall keep a copy of the EC declaration of conformity at disposal of the competent authority for 10 years after the product is placed on the market and provide a copy of the technical documentation to the competent authority upon its request.

Cases in which obligations of manufacturers apply to importers and distributors
Article 7- (1) The importers and the distributors who place a product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the requirements of the relevant technical legislation may be affected, shall be considered as a manufacturer for the purposes of this Regulation and shall assume the obligations of the manufacturer under Article 4.

CHAPTER III
Conformity Assessment Procedures, Affixing the CE Marking to the Product and Its Use and the EC Declaration of Conformity

Conformity assessment procedures
Article 8- (1) To be placed on the market a product shall be subject to the applicable conformity assessment procedures laid down in the relevant technical regulation(s) and undergo these procedures successfully.

Affixing the CE marking and its use

Article 9- (1) The general provisions on affixing the CE marking to the products and its use are as follows:

a) By affixing or having affixed the CE marking to the product, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant technical regulation(s) providing for affixing of the CE marking and that the product concerned has been subject to all required conformity assessment procedures.

b) Where a product falls in the scope of several technical regulations which require affixing of the CE marking, the CE marking on the product indicates that all applicable provisions of all relevant technical regulations have been fulfilled by the manufacturer. Where the technical regulations concerned give manufacturer the right to choose for an application during the transitional period, the CE marking indicates the conformity only with the provisions of the technical regulation(s) applied.

c) The CE marking shall;

1) consist of the initials "CE" taking the form in the diagram in Annex-1 and its design cannot be changed except for being reduced and enlarged respecting to the proportions given in this diagram,

2) be at least 5 mm high, where a relevant technical regulation does not impose specific dimensions,

3) be affixed visibly, legibly and indelibly to the product or to its data plate, where this is not possible or not warranted on account of the nature of the product, to the packaging and to the accompanying documents where the relevant technical regulation provides for such documents.

ç) The CE marking shall be affixed before the product is placed on the market.

d) The CE marking shall be affixed only by the manufacturer or his authorised representative.

e) Where the relevant technical regulation provides for, the CE marking shall be followed by the identification number of the notified body which is involved in the production control phase. The identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer, or his authorised representative.

f) The CE marking may be followed by a pictogram or any other mark indicating a special risk or the category of use, on product.

g) The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

ğ) CE Marking shall only be used on the products which the technical legislation requires for its affixing and not on any other products.

EC declaration of conformity
Article 10- (1) Without prejudice to relevant technical regulation, the EC declaration of conformity shall be drawn up so as to contain information that the relevant module(s) require at least and shall be in the form in Annex-2. In case the declaration is not in Turkish, its Turkish translation shall accompany the declaration. The declaration shall be updated, whenever it is necessary.

(2) Where a product is subject to more than one technical regulation providing for the EC declaration of conformity, the manufacturer indicates that he has fulfilled all applicable requirements of the relevant technical regulations drawing up just a single EC declaration of conformity. The declaration contains the name, the publication date and the reference number of those technical regulations to which the declaration relates.

(3) By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements of the technical regulation.

Modules for conformity assessment
Article 11- (1) **–** Where a technical regulation provides for conformity assessment for certain products, the procedure shall be chosen among the modules set out in Annex-3, without prejudice to Article 1(2).

(2) Which module(s) in the Annex-3 to be followed shall be specified in the relevant technical regulation.

CHAPTER IV
Miscellaneous Provisions

Equivalence of the authorised representatives established abroad
Article 12- (1) The authorised representatives established in a Member State of the European Union are accepted equivalent to the ones established in Turkey, without prejudice to the principle of reciprocity.

(2) Those authorized representatives established outside Turkey and the European Union shall be deemed equivalent to the ones established in Turkey, where a mutual recognition agreement between the European Union and the third country in which the authorized representative established exists and a parallel agreement between Turkey and that third country has been concluded and entered into force.

Application
Article 13- (1) The provisions of this Regulation shall be applied together with specific technical regulations providing for affixing the “CE” marking to the product.

Penalties
Article 14- For the persons who infringed the provisions of this Regulation, fines laid down in Law no 4703 shall be applied.

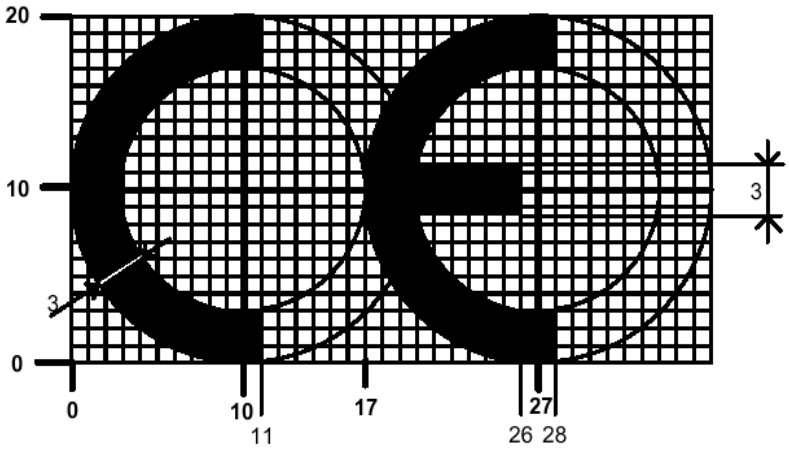
Repeal
Article 15 - (1) “Regulation on the Affixing and Use of the CE Marking on the Product”, which was put into force by the Decision of the Council of Ministers of 15/11/2001 and No:2001/3530 shall be repealed. References to the repealed Regulation shall be construed as references to this Regulation.

Entry into force
Article 16 - (1) This Regulation shall enter into force on the date its publication.

Implementation
Article 17 - (1) This Regulation shall be implemented by the Council of Ministers.

ANNEX-1
THE "CE" MARKING

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



2. If the CE marking is reduced or enlarged, the proportions given in the graduated drawing above shall be respected.

3. Where a relevant specific technical regulation does not impose specific dimensions, the CE marking shall be at least 5 mm high.

ANNEX-2
AN EXAMPLE OF EC DECLARATION OF CONFORMITY

1. No….(unique identification of the product)

2. The name and address of the manufacturer or his authorised representative

3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where
appropriate):

5. The object of the declaration described above is in conformity with the legislation (The name of the legislation)

6. References to the relevant harmonised national standards used or references to the specifications in relation to which conformity is declared:

7. Where applicable, the notified body ... (name, number) … performed … (description of intervention) … and issued the certificate: …

8. Additional information:

Signed for and on behalf of: ……
(place and date of issue):
(name, function) (signature):

ANNEX-3
CONFORMITY ASSESSMENT PROCEDURES

Please note that this annex has been directly transposed from the Annex II Decision No 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. Therefore, please refer to that text if the English version of the Annex-3 of this Regulation is needed.