

# CE Certification

[A collection of notes, text and pictures taken from several sources I made for personal use, about the topic of CE Marking. To speed up the process of writing I barely put references. This is but a rough-probably-with-some-mistakes guide. To be sure, do your own research.]

Last edited on 12.06.2021 by André Duarte B. L. Ferreira

## 1 Intro

Many products require CE certification (also called CE marking) before they can be sold in the European Economic Area (EEA). The CE marking indicates that a product has been assessed by at least the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then sold in the EEA.

For example, most electrical products must comply with the Low Voltage Directive, the EMC Directive, among others; toys must comply with the Toy Safety Directive. (The Low Voltage Directive is about electrical safety; EMC or Electromagnetic Compatibility[6] means the device will work as intended without interfering with, or being affected by, the use or function of any other device.)

## 2 CE Certification Process

The CE certification process consists of six steps that must be completed before we can apply the CE label to our product and sell it on the EEA:



Fig. 1 The 6 steps that the CE certification process consists of.

### 2.1 Identify applicable directive(s)

The first step is to identify whether your product can be CE marked or not. Not all products are required to be CE Marked, only the products that fall within the scope of at least one of the **CE Marking Directives** need to. There are more than 20 product directives & regulations covering a

range of products. Such products include (but are not limited to) electrical equipment, machines, medical devices, toys, pressure equipment, PPE, wireless devices and construction products.

Identifying which directive(s) may be applicable, as there may be more than one, involves a simple exercise of reading the scope of each directive (such as the "Low Voltage Directive," 2014/35/EU). If the product does not fall within the scope of any of the directives, then the product does not need to bear CE marking (and, indeed, must **not** bear the CE marking).

Determining whether your product falls under one or more directives can be difficult. For example, if you manufacture electronic packaging machines with a conveyer belt, several directives will impact you. If you want to know which directives apply, you will have to go through each of the 24 directives (product coverage is sometimes found in an annex). Unfortunately, there is no reference tool or database that lists which directives might be applicable to certain products.

[https://ec.europa.eu/growth/single-market/ce-marking/manufacturers\\_en](https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en)

product only once this has been done.


## Product groups

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- Active implantable medical devices
- Appliances burning gaseous fuels
- Cableway installations designed to carry persons
- Construction products
- Ecodesign of energy related products

### Directives

If your product(s) fall(s) within the sector of energy-related products, it (they) might be subject to Directive 2009/125/EC on the Ecodesign of energy related products (the 'ecodesign directive'):

- [Directive 2009/125/EC on the ecodesign of energy related products](#) 
- [Factsheet: Ecodesign your future](#)
- For more information on Directive 2009/125/EC on ecodesign, please also visit the [ecodesign webpage](#)
- See more on [harmonised standards for the ecodesign of energy related products](#)

**Fig. 2** Example on where to find one directive by following the link above. It's also a good idea to read the description below as it contains a good summary of the directive.

**Note:** 'Directive 2009/125/EC' means it was published on 2009, the document number is 125 (it's just a sequential number given to docs published in that year) from the European Council / Commission (not sure which).

This website kind of makes it easier to find the applicable directives: <https://ce-tool.com/en/selection-active.html>

29.3.2014	EN	Official Journal of the European Union	L 96/357
<b>DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL</b> <b>of 26 February 2014</b> <b>on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits</b> <b>(recast)</b> <b>(Text with EEA relevance)</b>			
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,			
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,			
Having regard to the proposal from the European Commission,			
After transmission of the draft legislative act to the national parliaments,			
Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup> ,			
Acting in accordance with the ordinary legislative procedure <sup>(2)</sup> ,			
Whereas:			

Fig. 3 As an example, what the beginning of the directive for low voltage products looks like.

## 2.2 Identify the applicable requirements of the directive(s)

Each directive has slightly different methods of demonstrating conformity. This usually depends on the classification of the product and its intended use. Every directive has a number of 'essential requirements' which the product has to meet.

- (a) any economic operator who has supplied them with a toy;
- (b) any economic operator to whom they have supplied a toy.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after the toy has been placed on the market, in the case of the manufacturer, and for a period of 10 years after they have been supplied with the toy, in the case of other economic operators.

### CHAPTER III CONFORMITY OF TOYS

#### *Article 10*

#### Essential safety requirements

1. Member States shall take all measures necessary to ensure that toys may not be placed on the market unless they comply with the essential safety requirements set out, as far as the general safety requirement is concerned, in paragraph 2, and, as far as the particular safety requirements are concerned, in Annex II.
2. Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

The ability of the users and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups.

Labels affixed in accordance with Article 11(2) and instructions for use which accompany toys shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to

**Fig. 4** “Essential safety requirements” sometimes can be found in one of the main chapters of the directive. Other times in the annexes. Taken from directive 2009/48/EC.

The best way to demonstrate that these essential requirements have been met is by meeting the requirements of applicable ‘**harmonised European Norms**’ (standards) known as hENs.

[https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards\\_en](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en)

## Harmonised Standards

**A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.**

The references of harmonised standards must be published in the Official Journal of the European Union. The purpose of this website is to **provide access to the latest lists of references of harmonised standards** and other European standards published in the Official Journal of the European Union (OJEU).

### References of harmonised standards and of other European standards published in the OJEU

#### Accessibility

- [Websites and mobile applications of public sector bodies](#)

Product categories  
(same as directives)

#### Chemicals

- [Chemical substances \(REACH\)](#)
- [Explosives for civil uses](#)
- [Pyrotechnic articles](#)

If we go to one of them (let's say the toy ones)

## Toy safety

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Directive 2009/48/EC

Short name:	<b>Toy safety</b>
Base:	<a href="#">Directive 2009/48/EC</a> of the European Parliament and of the Council of 18 June 2009 on the safety of toys OJ L 170, 30 June 2009
Modification:	[-]
Directives repealed:	<a href="#">Council Directive 88/378/EEC</a> of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys OJ L 187 of 6 July 1988 Directive 88/378/EEC, except Article 2(1) and Part 3 of Annex II, is repealed with effect from 20 July 2011. Article 2(1) thereof and Part 3 of Annex II thereto are repealed with effect from 20 July 2013.
Guide for application:	<ul style="list-style-type: none"> <li>• <a href="#">Guidance on CE marking for professionals</a></li> <li>• <a href="#">Guidance documents from the expert group on toy safety</a></li> </ul>
European Commission contact point:	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs Email: <a href="mailto:GROW-TOYS@ec.europa.eu">GROW-TOYS@ec.europa.eu</a> Webpage on <a href="#">toys</a>

For information about the content and availability of European standards, please contact the [European Standardisation Organisations](#).


Since 1 December 2018 the references of harmonised standards are published in, and withdrawn from the Official Journal of the European Union by means of 'Commission implementing decisions'.

The references published under Directive 2009/48/EC on toy safety are found in the Commission Implementing Decision(s) listed below. The summary list below gives a consolidated overview on all publications in the Official Journal.

EN version

Publications in the Official Journal:

[Commission Implementing Decision \(EU\) 2019/1728 of 15 October 2019 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council C/2019/7315 - OJ L 263 of 16 October 2019, p. 32–35](#)

[be](#) [ca](#) [da](#) [de](#) [el](#) [en](#) [es](#) [et](#) [fi](#) [fr](#) [hr](#) [hu](#) [it](#) [lt](#) [lv](#) [nl](#) [pl](#) [pt](#) [ro](#) [sk](#) [sl](#) [sv](#) 

L 263/32	EN	Official Journal of the European Union	16.10.2019
<p><b>COMMISSION IMPLEMENTING DECISION (EU) 2019/1728</b>  <b>of 15 October 2019</b>  <b>on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council</b></p>			
<p>THE EUROPEAN COMMISSION,</p> <p>Having regard to the Treaty on the Functioning of the European Union,</p> <p>Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council <sup>(1)</sup>, and in particular Article 10(6) thereof,</p> <p>Whereas:</p> <p>(1) In accordance with Article 13 of Directive 2009/48/EC of the European Parliament and of the Council <sup>(2)</sup>, toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to conform with the essential requirements of that Directive.</p>			

Where if we scroll a bit, at the bottom in the annex we can find the standards we're looking for.

L 263/34	EN	Official Journal of the European Union	16.10.2019
ANNEX I			
No	Reference of the standard		
1.	EN 71-1:2014+A1:2018 Safety of toys — Part 1: Mechanical and physical properties		
2.	EN 71-2:2011+A1:2014 Safety of toys — Part 2: Flammability		
3.	EN 71-3:2019 Safety of toys - Part 3: Migration of certain elements		
4.	EN 71-4:2013 Safety of toys — Part 4: Experimental sets for chemistry and related activities		
5.	EN 71-5:2015 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets		
1.	EN 71-7:2014+A2:2018 Safety of toys — Part 7: Finger paints — Requirements and test methods Note: For the allowed preservative climbazole (entry 22 in Table B.1 of Annex B to this standard) the presumption of conformity applies up to a maximum allowed concentration of 0,2 % (not: 0,5 %). This is based on the 'ADDENDUM to the Opinion on Climbazole (P64) ref. SCCS/1506/13' of the Scientific Committee on Consumer Safety (SCCS) that was adopted after the publication of the standard by CEN. <a href="https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_212.pdf">https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_212.pdf</a>		
2.	EN 71-8:2018 Safety of toys — Part 8: Activity toys for domestic use		
3.	EN 71-12:2013 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances		
4.	EN 71-13:2014 Safety of toys — Part 13: Olfactory board games, cosmetic kits and gustative games		
5.	EN 71-14:2018 Safety of toys - Part 14: Trampolines for domestic use		

In many cases, manufacturers may rely on standards other than harmonized standards in order to demonstrate compliance with the essential requirements in the directives.

You may ask, “Why don't we just meet the essential requirements directly?” Because many times they're written in a broad way. For example, an essential requirement might say (in other words) “it must be safe for children”. Nice, but how do we make sure it's safe for children? In the hENs we can see more explicitly what features the product must have, or what does it need to have in mind or tests to be made to make sure it is safe for children.

A harmonized standard can cost anywhere from 300 to 1,500 Euros. While a manufacturer does not need to buy these documents to meet the essential requirements of the directive, European

authorities often use them to determine whether a product meets the essential requirements. Working from the same document can help us to avoid potential technical disputes over whether our product meets the essential requirements of the directive. Again, essential requirements are often vague – leaving lots of room for technical interpretation.

## 2.3 Find out how conformity is to be evaluated

In order to be eligible to affix the CE Marking we may have to involve a third party. This will vary between directive. For products that present higher safety risks such as gas boilers, invasive medical devices or fire alarm systems, safety cannot be checked by the manufacturer alone. In these cases, an independent organisation, specifically a third party appointed by national authorities, has to perform the safety check. We call these third parties 'Notified Bodies'.

(9) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer. There is no conformity assessment procedure in this Directive which requires the intervention of a notified body.

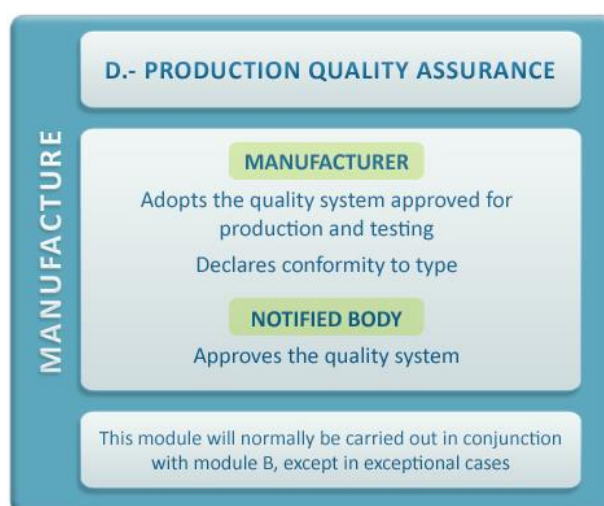
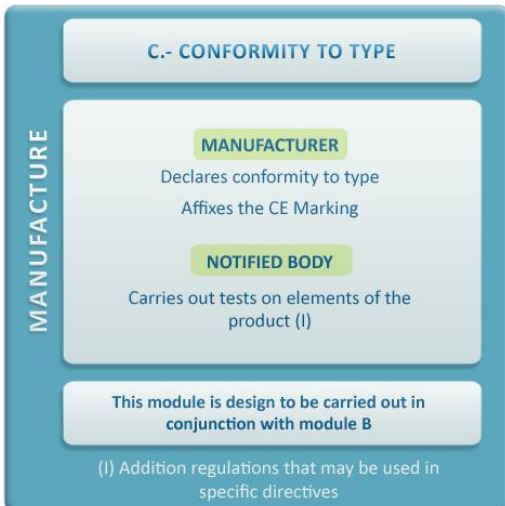
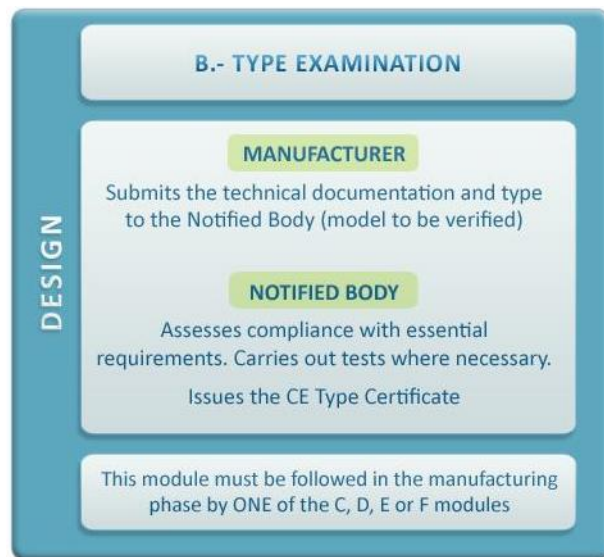
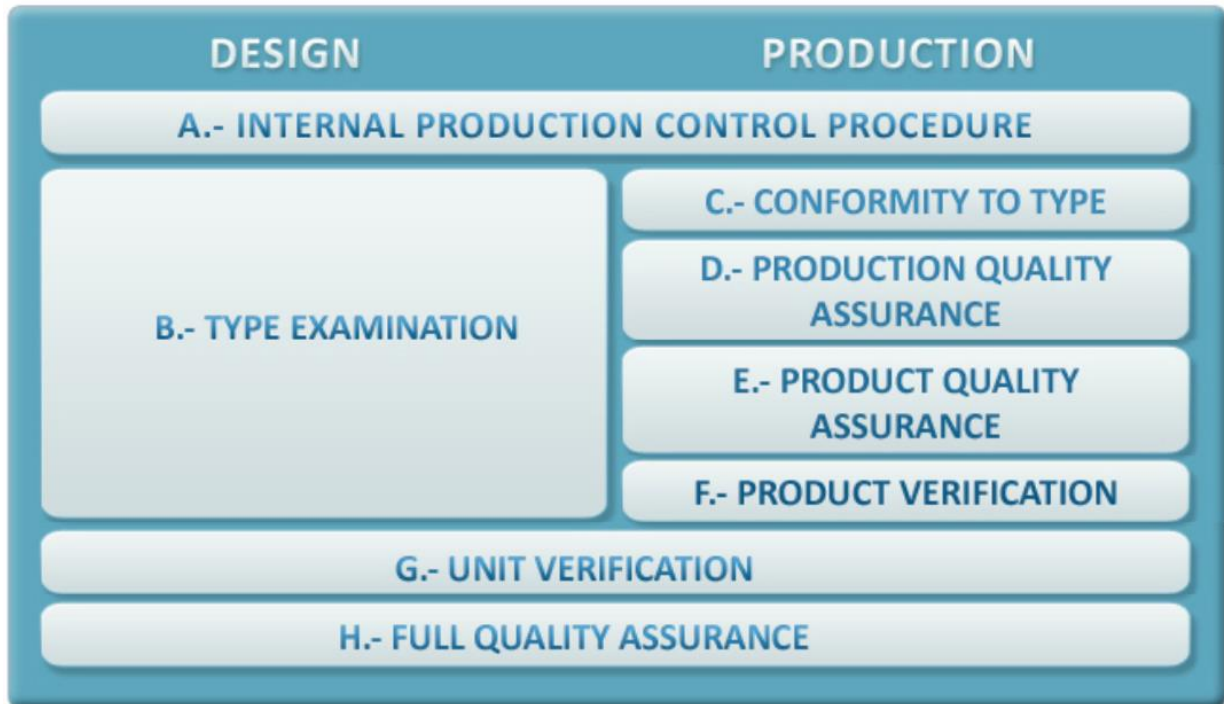
Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes; whereas the classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices; whereas the conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products; whereas, for Class IIa devices, the intervention of a notified body should be compulsory at the production stage; whereas, for devices falling within Classes IIb and III which constitute a high risk potential, inspection by a notified body is required with regard to the design and manufacture of the devices; whereas Class III is set aside for the most critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market;

**Fig. 5 Top)** Excerpt from Directive 2014/35/EU on Low Voltage asserting that there's no need for notified body to intervene; **Bottom)** Excerpt from Directive 93/42/EEC on Medical Devices asserting some conditions in which a notified body is required.

When going through a directive we might see the word 'module' being mentioned (**Fig. 6**). A module specifies how the conformity assessment is to be performed. From module A, internal production control, until module H, full quality assurance by a notified body. Depending on the type of product and the safety risks, a certain module has to be followed. In addition, the procedure is further broken down into modules relating to the design and production phase, as shown in the diagram below.

There are two main phases for conformity assessment, one during the design of the product and one during/after its production:

- Design assessment (of a prototype or a sample of the product) by way of relevant tests and studies.
- Production assessment (all product units must continue to comply in the same way as the sample studied in the design assessment phase), through control of production quality, preferably based on ISO 9001.2000 standards.





Source

Looking at the Directive we discover that we have to apply Module A in those conditions:

<i>Article 19</i>	
<b>Applicable conformity assessment procedures</b>	
1.	Before placing a toy on the market, manufacturers shall use the conformity assessment procedures referred to in paragraphs 2 and 3 to demonstrate that the toy complies with the requirements set out in Article 10 and Annex II.
2.	If the manufacturer has applied harmonised standards, the reference number of which has been published in the <i>Official Journal of the European Union</i> , covering all relevant safety requirements for the toy, it shall use the internal production control procedure set out in Module A of Annex II to Decision No 768/2008/EC.
3.	In the following cases, the toy shall be submitted to EC-type examination, as referred to in Article 20, together with the conformity to type procedure set out in Module C of Annex II to Decision No 768/2008/EC:
(a)	where harmonised standards, the reference number of which has been published in the <i>Official Journal of the European Union</i> , covering all relevant safety requirements for the toy, do not exist;

Fig. 6 Excerpt of directive 2009/48/EC for safety of toys stating which modules need to be applied to test for conformity.

So if we look up that document "Decision No 768/2008/EC"

13.8.2008

EN

Official Journal of the European Union

L 218/82

**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**  
**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,  
 Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,  
 Having regard to the proposal from the Commission,  
 Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,  
 After consulting the Committee of the Regions,

And scroll down to the Annex II, we find what that module actual entails:

**ANNEX II**

**CONFORMITY ASSESSMENT PROCEDURES**

**Module A**

**Internal production control**

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.
2. Technical documentation
 

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

  - a general description of the product,

Module A is the only one that may not require a Notified Body. In this case, the whole certification process can then be made in-house, with no external help, so we sometimes call it 'self-certification'.

To find a notified body use Nando (New Approach Notified and Designated Organisations) Information System:

<https://ec.europa.eu/growth/tools-databases/nando/>

## 2.4 Assess the product's conformity

When we've established what all of the applicable requirements for the applicable directives are and how conformity is going to be tested, the next phase is evaluate whether the product conforms or not to those requirements.

To assess which risks can arise and whether the essential safety requirements will be met, a risk analysis (FMEA) should be conducted.

It will also often involve ensuring that the requirements of the applicable harmonised standard(s), which were identified in step 2, have been met.

Finally it may or may not require some sort of testing on the prototype, on the actual product, or on the manufacturing process, as seen in the previous chapter.

Now that our product has been tested and meets all relevant European Community standards, it's time for our technical documentation to be in order. Ideally this step started already earlier, but is just now (because only now do we have all the data) going to be finalized.

## 2.5 Compile the technical documentation

Technical documentation relating to the product or range of products needs to be compiled. This information should cover every aspect relating to conformity and is likely to include details of the design, development and manufacture of the product. Technical documentation may also be known as the Technical File or Technical Construction File.

Technical documentation will usually include:

- Technical description;
- Drawings, circuit diagrams and photos;
- Bill of materials;
- Specification and, where applicable, Declarations of Conformity for the critical components and materials used;
- Necessary drawings and documentation pertaining to product design incl. supporting documents- calculations, simulations, etc.;
- Description and explanations that further clarify the above-mentioned information;
- Installation and user manual in languages of the target EU countries;
- Test reports and/or assessments;
- Copy of the Declaration.

Technical documentation can be made available in any format (i.e. paper or electronic) and must be held for a period of up to 10 years after the manufacture of the last unit, and in most cases reside in the European Economic Area (EEA). Typically, all certification bodies accept technical documentation in English.

## 2.6 Make a declaration and affix the CE mark

When the manufacturer, importer or authorised representative is satisfied that their product conforms to the applicable CE Marking Directives, they must complete a declaration. Under most Directives it is known as the EU Declaration of Conformity but other terms exist. The Declaration (certificate) of Conformity is a signed legal document which certifies that the product fulfils all the essential requirements of the applicable CE Directives and other relevant standards.

It is the responsibility of the manufacturer/importer to produce this once the technical file is ready.


The requirements for the Declaration vary slightly, but will at least include:

- Name and address of the manufacturer;
- Details of the product (model, description and the serial number where applicable);




- List of CE Marking Directives and standards that have been followed;
- A statement declaring that the product complies with all of the relevant requirements;
- Details of the authorised representative within the EEA (where applicable);
- Additional Directive/standard specific requirements;
- Signature, name and position of the responsible person;
- The date that the Declaration was signed.

In all cases, except for the PPE Directive, all of the Directives can be declared on one Declaration.

Once a Declaration has been completed, the final step is to affix the CE mark to the product. When this has been done and all of the other CE Marking requirements have been met, the product can then be legally placed on the EU market.

<b>Declaration of Conformity</b> <small>The declaration of conformity is issued under the sole responsibility of the manufacturer</small>	
<b>Issuer</b> Business name: Address: Country:	<b>Product</b> Name: Model: Serial number: Description:
<b>Product photo:</b> 	
We declare that the product described above, to which this declaration of conformity refers to, is in conformity with the essential requirements of the following legislation: - 2014/30/EU Electromagnetic Compatibility Directive (EMC) (example) through the technical standards/specifications specified below: - EN 61000-3-2:2014 - Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (example)	
Signed for and on behalf of	
_____	_____
<small>Date and place of issue</small>	<small>Name and title</small>
_____	
<small>Signature</small>	

 <b>DECLARATION OF CONFORMITY</b>	
We:	TOA Electronics Europe GmbH Süderstraße 282, 20537 Hamburg, Germany
as the authorised representative of the	
Manufacturer:	TOA Corporation 7-2-1, Minatojima-nakamachi, Chuo-ku, Kobe, Japan 650-0046
declare, under our sole responsibility, that the product	
Product Name:	WALL MOUNT SPEAKER
Model Number:	BS-1034EN
conforms with following specifications:	
EMC:	EN 61000-6-1(2007) EN 61000-6-3(2007)
CPD:	EN 54-24:2008 Certificate no.: 0359-CPD-0102
The product herewith complies with the requirements of the EU directives: 2004/108/EC relating to electromagnetic compatibility (EMC), 89/106/EEC relating to requirements on construction products (CPD), 2002/95/EC relating to the restrictions of hazardous substances (RoHS)	
Remark: This Declaration of Conformity replaces all previous ones of the above model(s).	
	
Hamburg, 20 <sup>th</sup> June 2011 <small>(place, date)</small>	 T. Sakata, Managing Director <small>(authorised signature)</small>
<small>The Technical Construction File (TCF) is kept at the UK office:</small>	
TOA Corporation (UK) Ltd, HQ3, Unit 2, Hook Rise South, Surbiton, Surrey KT6 7LD; United Kingdom Tel: +44 (0) 870 774 0987; Fax: +44 (0) 870 777 0839; URL: www.toa.co.uk	
<small>German Office:</small>	
TOA Electronics Europe GmbH, Süderstraße 282, 20537 Hamburg, Germany Tel: +49 / (0)40 / 25 17 19-0, Fax: +49 / (0)40 / 25 17 19-98 URL: www.toa.eu	

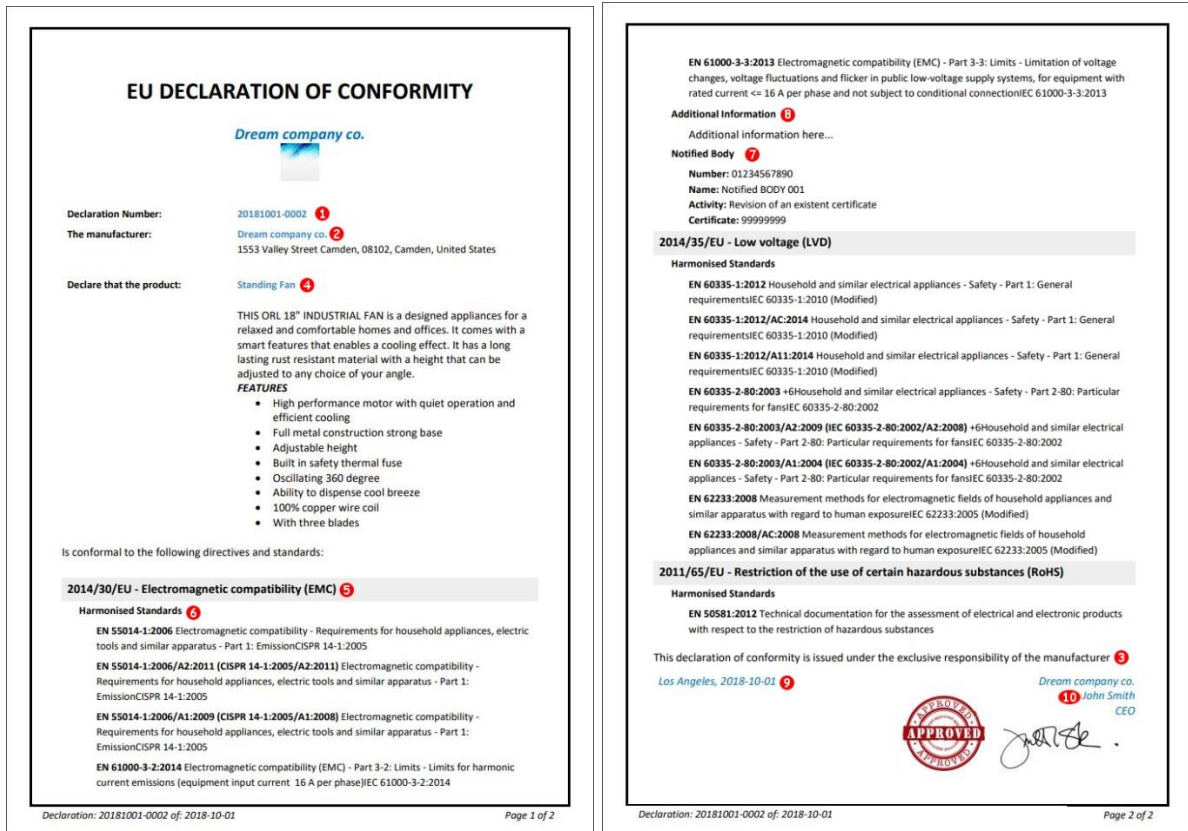


Fig. 7 Example of what a Declaration of Conformity can look like.

The CE mark or CE label consists of the **CE symbol** and, if applicable, the four digit identification number of the Notified Body involved in the conformity assessment procedure.



Fig. 8 CE symbol design and a CE label imprinted/stickied on products.

### 3 FAQ

#### 3.1 Is there a fee in the CE marking process?

If the manufacturer carries out the CE marking process by himself, no fee is involved. If a Notified Body is involved, they charge for their services depending on the complexity of the task.

#### 3.2 What is a ‘Notified Body’?

A Notified Body is an entity authorized by European authorities to assess a product’s conformity to the essential requirements set out in the applicable directives.

Some EU Directives require the intervention of notified bodies to fulfill the requirements of CE markings, whereas others may not. Involving their expertise at an early stage of the CE marking process can make it faster and simpler.

### 3.3 Who bears the responsibility of having the CE mark?

Importers of products have to verify that the manufacturer outside the EEA has undertaken the necessary steps and that the documentation is available upon request. Importers should also make sure that contact with the manufacturer can always be established.

If importers or distributors market the products under their own name, they take over the manufacturer's responsibilities. In this case they must have sufficient information on the design and production of the product, as they will be assuming the legal responsibility when they affix the CE marking.

[https://ec.europa.eu/growth/single-market/ce-marking/importers-distributors\\_en](https://ec.europa.eu/growth/single-market/ce-marking/importers-distributors_en)

### 3.4 What is a directive?

A directive is a legislative act of the European Union which requires member states to adapt their national laws to achieve a particular result that is harmonized to EU rules in this area.

For example, the EU directive for products which fall under the electromagnetic compatibility category (directive number 2004/108/EC) calls for member states to ensure that electrical devices that fall under this category meet certain requirements

### 3.5 What is a harmonized standard?

A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.

## 4 Useful links

[https://ec.europa.eu/growth/single-market/ce-marking\\_en](https://ec.europa.eu/growth/single-market/ce-marking_en)

[https://ec.europa.eu/growth/single-market/ce-marking/manufacturers\\_en](https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en)

[https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards\\_en](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en)

<https://ce-marking.help/>