

# CE MARKING PRODUCTS

WHY  
HOW  
WHO  
WHEN

CE

# Administration of Occupational Safety and Health

The Administration of Occupational Safety and Health (AOSH) is an independent institution under the Ministry of Social Affairs. It's role is to prevent accidents and health damage in the workplace.



Ágúst Ágústsson  
Senior Specialist

# Why

To put a product on the market in Europe.

The product must fulfill the

- Essential health and safety requirement in the relevant directive
- There are many Directives, we are the market surveillance authority for some of them like the
- **Machinery directive 2006/42/EC - MC**
  - Pressure equipment directive 2014/68/EC - PED
  - Gas appliances 2016/426/EC - GAR
  - Transportable pressure equipment 2010/35/EC - TPED

# Why

New approach.

New Directives in Europe, merged from many regulations.  
Each country had their own set of rules.

Essential health and safety requirements relating to the the design and construction of machinery. (Annex I in 2006/42/EC)

Harmonised standards

CE marked products shall be safe for the user.

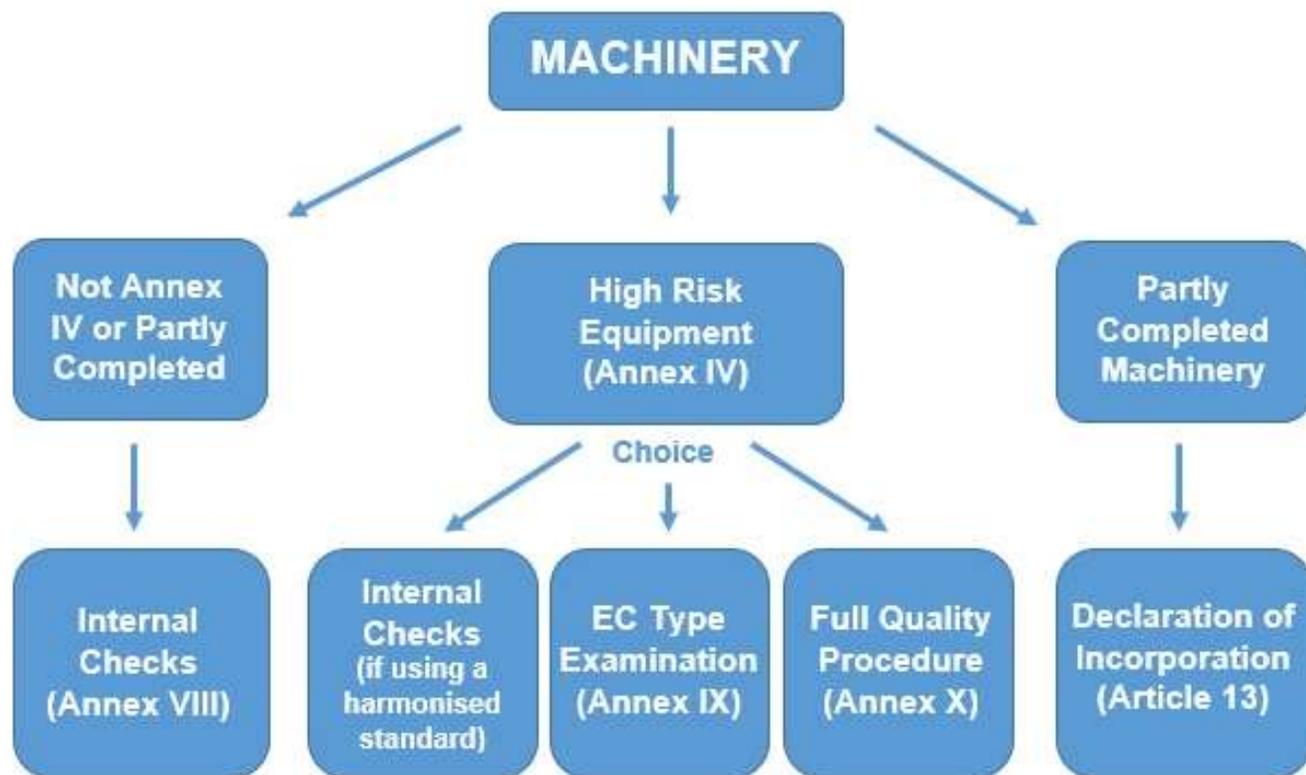
# How

## Follow the Directive

### A guideline on the website

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

1. Identify the applicable directive(s) and [harmonised standards](#)
2. Verify product specific requirements
3. Identify whether an independent [conformity assessment](#) (by a notified body) is necessary ( Annex IV)
4. Test the product and check its conformity
5. Draw up and keep available the required **technical documentation**
6. Affix the [CE marking](#) and draw up the [EU Declaration of Conformity](#) .



## Technical documentation or technical file for Machinery ANNEX VII

(a) a construction file including:

- a general description of the machinery,
- the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
- full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,
- the documentation on **risk assessment** demonstrating the procedure followed, including:
  - (i) a list of the essential health and safety requirements which apply to the machinery,
  - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,

- the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
- any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
- a copy of the instructions for the machinery,
- where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,
- where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,
- a copy of the EC declaration of conformity;

## **EU Declaration of Conformity Annex II.**

The EC declaration of conformity must contain the following particulars:

1. business name and full address of the manufacturer and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the technical file, who must be established in the Community;
3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the Official Journal of the European Union;

5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Annex IX and the number of the EC type-examination certificate;
6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X;
7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2);
8. where appropriate, the reference to other technical standards and specifications used;
9. the place and date of the declaration;
10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

# Who

The manufacturer or his authorised representative.

The manufacturer of Machinery ( Directive 2006/42) can in most cases make the conformity assessment and compile the technical documentation

And CE mark his product.

Only when the product falls under Annex IV does he have to have a notified body or make his product according to a harmonised standard.

For example the standard for EPAC cycles EN 15194:2017 is harmonised standard.

# When

*Article 5 in the directive 2006/42/EC*

Placing on the market and putting into service

1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:

- (a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;
  - (b) ensure that the technical file referred to in Annex VII, part A is available;
  - (c) provide, in particular, the necessary information, such as instructions;
  - (d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;
  - (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;
  - (f) affix the CE marking in accordance with Article 16.
-

# Finished