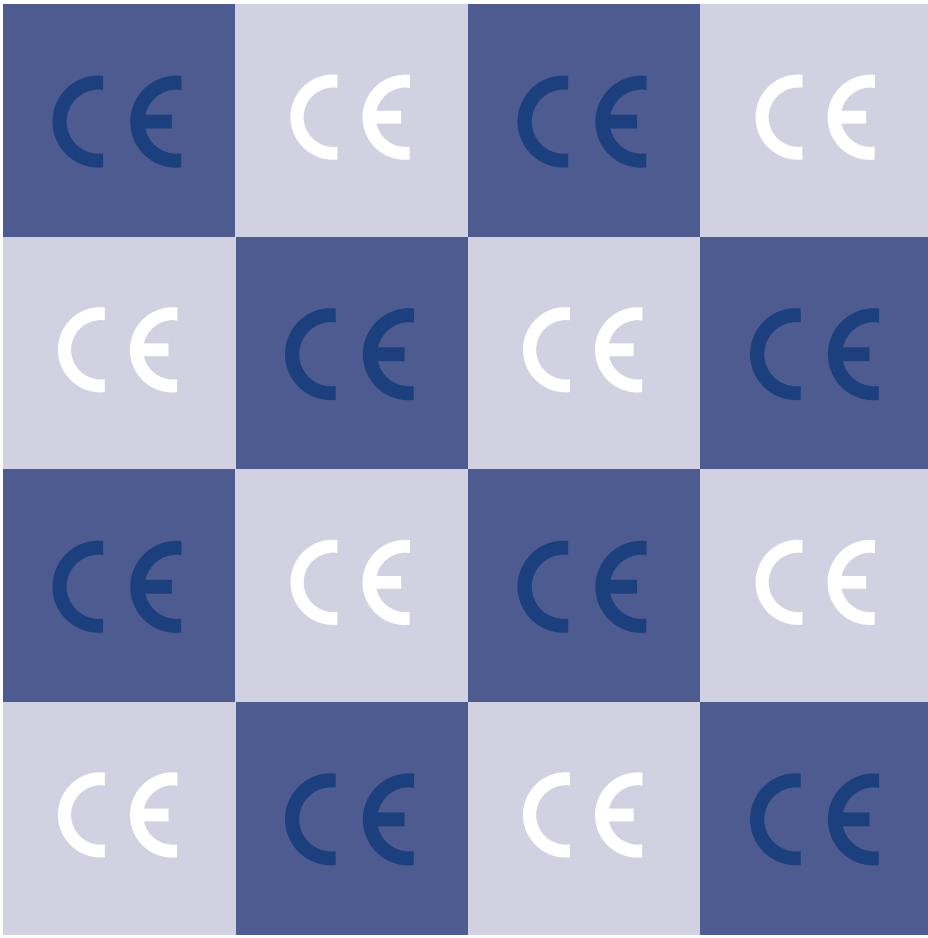
CE Mark Guide



This guide tells you everything you need to know about the CE Mark as it relates to all Personal Protective Equipment, including

- The meaning of the CE Mark
- PPE Performance
- Certification procedures
- Product categories
- Types of Documentation

In brief, it is clear, concise and invaluable reference tool

CE

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What is the meaning of a CE mark on Personal Protective Equipment?

The European Directive 89/686/EEC lays down the requirements for CE marking of personal protective equipment (PPE).

CE marking can, in simple terms, be described as a passport or 'license to sell' allowing free movement of goods within the internal market of the European Community.

It simplifies the task of market surveillance but also informs all market operators (consumers, manufacturers, tradesmen) that the product meets the essential requirements relating to safety, public health, consumer protection and other specific aspects of community interest laid down in the directives.

Amendments of Dir 89/686/EEC:

93/68/EEC	- CE not EC in text
93/95/EEC	- Products covered
96/58/EEC	- CE mark changes

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When will PPE need a CE mark?

After May 1st 2004 the CE mark will be compulsory for all PPE placed on the market.

All our products are already CE marked.

PPE without a CE mark already in use before this date can continue to be used. When the product becomes worn out or broken and you need to buy new equipment, it must be CE marked.

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Does the CE mark tell me anything about the performance of the PPE?

The technical performance of PPE is specified by European Norms, harmonized standards or in a technical file when harmonized standard does not exists.

Very often you will find reference to this European Norm as additional information on the product, the packaging or other documentation.

This information is important to better understand the different performance classes and/or types of the PPE in use

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Is the CE mark a quality symbol?

No, all CE marked PPE has to be submitted to the appropriate conformity assessment evaluation procedures according to the directive.

(See questions for details of the methods)

Only in certain cases can the procedure for maintaining a CE mark to be considered equivalent to that required for the quality mark.

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What certification procedures are in place for different types of PPE?

The directive 89/686/EEC divides all PPE into three different categories according to the degree of risk. The higher the risk the PPE needs to protect against, the more stringent the certification procedure.

Category I

All PPE protecting against minimal risks, where the user himself/herself can assess the level of protection needed, or where the effects are gradual and can safely be identified by the user in good time.
e.g. gardening gloves, sunglasses, garments and footwear designed for use in bad weather conditions.

Certification Process:
The manufacturer has to assemble the technical documentation so that this can, if necessary, be submitted to the competent authorities = self declaration by means of EC declaration of conformity.

Category I products would be marked as follows: CE

Category II

- Head, face, eye protectors, garments, shoes and gloves protecting against normal risks
- All hearing protectors

Certification Process:
The manufacturer submits a model for EC type-examination, whereby an approved inspection body (notified body) establishes and certifies that the PPE-model in question satisfies the relevant provisions of the directive.

Marking of Category II products: CE

Category III

All PPE intended to protect against mortal danger or against dangers which may seriously and irreversible damage health, or where the effects cannot be identified in sufficient time.
e.g. respirators, fall arrestors

All other PPE protecting against:
- extreme heat (>100°C)
- extreme cold (< - 50°C)
- electrical risks
- chemical and ionising radiation

Certification Procedure:
On top of the type EC examination required for category II products, the manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and test ensures the homogeneity of the conformity of PPE with the type described in the EC type-approval.

This can be done in 2 ways:
1. EC quality control system for the final product: necessary checks shall be carried out by a notified body at random, normally at intervals of at least a year. Art. 11A
2. System for ensuring EC quality of production by means of monitoring: installation of a quality control system under supervision of a notified body Art. 11B

Marking of Category III products: e.g. CE 0086

0086 is the identification number of the notified body involved in the production control phase.

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IMPORTANT REMARK

Are there any documents that support the CE marking of PPE in use?

Yes, 3 documents can be obtained from 3M on request in order to complete your files on PPE in use.

EC-type examination certificate drawn up by the inspection body reproducing the findings of the examination on 3M products.

Declaration of conformity in which 3M certifies that the PPE placed on the market is in conformity with the directive

Quality control certificate: certifies the quality control system in place in 3M's production facilities.

SOME USEFUL WEBSITES

http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/index.htm

On this site of the European Commission you can find a lot of interesting information on the different categories of Personal Protective Equipment (PPE).

- Guide for the categorization of Personal Protective Equipment PPE
- Interpretations of the PPE directive
- Recommendation for use sheets
- General information on notified bodies
- List of notified bodies
- Working paper Draft proposal for an amending Directive to Directive 89/686/EEC
- FAQ
- Amendments

http://www.newapproach.org/Directives/Default.asp

This site provides the texts and additional information on the EN Standards

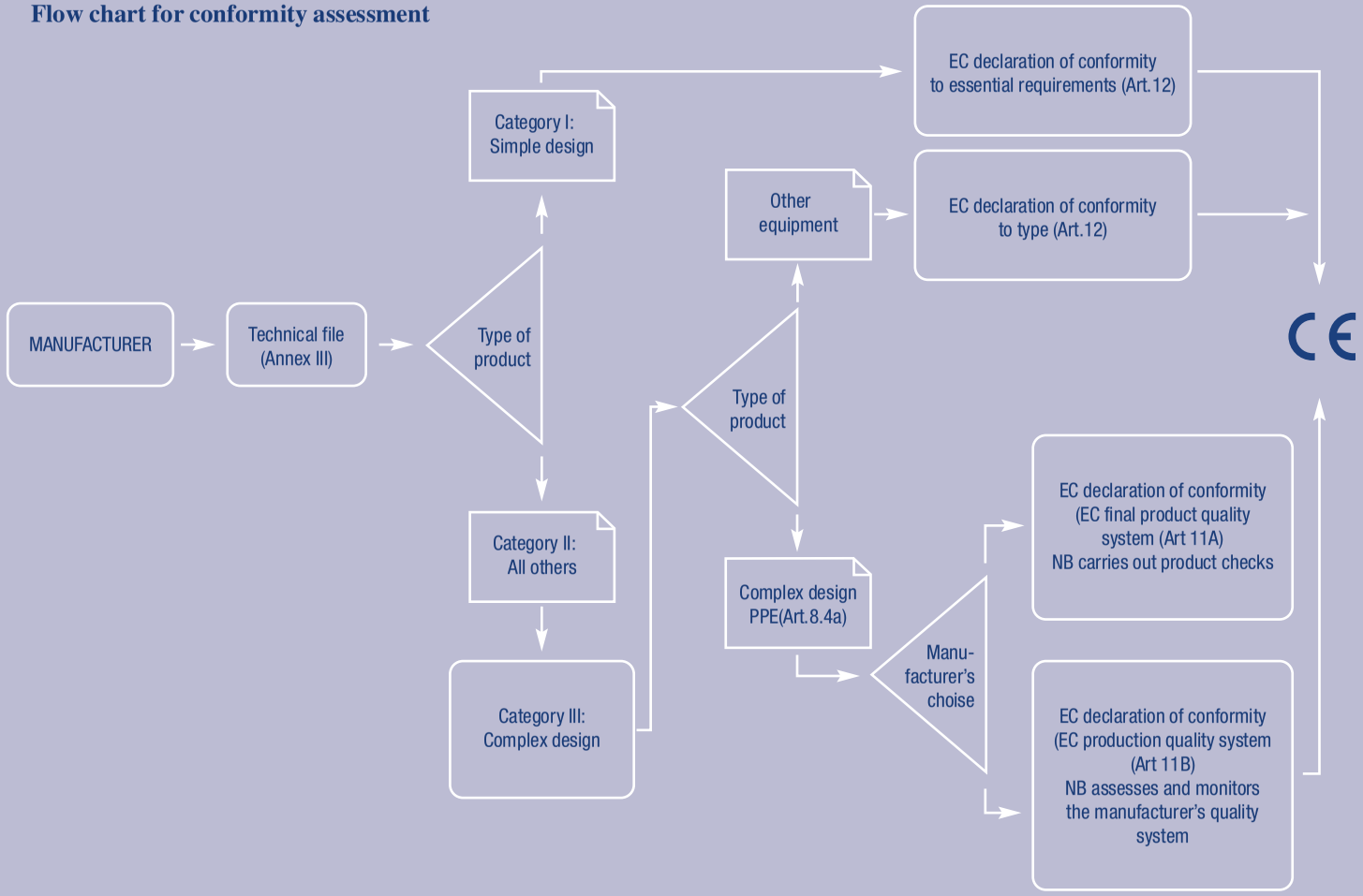
http://europa.eu.int/comm/employment_social/health_safety/intro/framedir_en.htm

The text of the Health and safety at work frame work Directive

http://nl.osha.eu.int/legislation/eu/directives.stm

The text of 89/656/EEC :Minimum health and Safety requirements for the use by workers of Personal protective equipment

Flow chart for conformity assessment



3M Belgium

Occupational Health & Safety Products
Guy Vangeel
Governmental Affaires Manager EEMENA
Hermeslaan 7
1831 Diegem
Tel.: 0032-2-722 52 18
Fax: 0032-2-722 50 38
E-mail: gvangeel@mmm.com