CE MARKING FOR PERSONAL PROTECTIVE EQUIPMENT

A Practical Guideline for Manufacturers and Procurement Bodies

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Registered offices
Bonn and Eschborn
Global Project Quality Infrastructure
Country Component India

Address
B5/2, 4th Floor, Safdarjung Enclave
New Delhi 110029, India

T +91 11 4949 5353
E qi-india@giz.de
I www.gpqi.org | www.giz.de/en/worldwide/32230.html

Editors
Vera Moser, Alok Kesari

Design
Seema Sethi Design LLP, New Delhi, India

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Federal Ministry
for Economic Affairs
and Energy

Implemented by
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für Internationale
Zusammenarbeit (GIZ) GmbH

CE MARKING FOR PERSONAL PROTECTIVE EQUIPMENT – A PRACTICAL GUIDELINE FOR MANUFACTURERS AND PROCUREMENT BODIES

In the past months, demand and supply of personal protective equipment (PPE), such as protective masks, face shields or coveralls, has increased significantly worldwide. PPE that meets the relevant quality and safety requirements is crucial in the response to the COVID-19 pandemic. CE marking is required to place PPE on the European market.

This practical guideline provides orientation regarding the CE marking of PPE. It is aimed at manufacturers, users, and procurement bodies of PPE. The guideline includes information on what the CE marking is and how its authenticity can be assessed. It also provides an overview of the key steps in the process of affixing the CE marking on PPE according to European Union (EU) Regulation 2016/425.

WHAT IS CE MARKING?

CE marking is the visible self-declaration by a manufacturer that the product conforms to the safety, health, and environmental protection requirements set by the European Union (EU) and has successfully undergone the required conformity assessment procedure.

CE marking is required for products manufactured anywhere in the world if they are to be marketed on the EU single market.[1] It is mandatory for those products for which EU specifications exist and the applicable legislation requires the affixing of CE marking - such as in the case of PPE.

CE marking lies in the responsibility of the manufacturer. By affixing the CE mark, manufacturers declare their sole liability and responsibility that the product conforms to all applicable EU legislative requirements. Depending on the risk category of a product, which is laid down in the specific applicable EU legislation, mandatory third-party testing by a designated conformity assessment body (notified body) may be required to demonstrate compliance with the legal requirements and may therefore be a prerequisite for the CE marking. Products bearing a CE mark can be made available and benefit from free movement of goods on the EU single market. The CE marking helps customs and market surveillance authorities in checking and, if necessary, withdrawing non-conforming products from the market.

CE

The CE marking is affixed by the manufacturer and is a self-declaration of conformity. The CE marking does not mean that a product has been checked by an official authority. Hence, it is not proof of a product's compliance with EU legislation. Contrary to common belief, the CE marking is not directed at consumers. The CE marking is a kind of passport for goods which allows them to enter and move freely on the EU single market.

The general principles governing the CE marking are set out in Regulation (EC) 765/2008 (amended Regulation (EU) 1020/2019 applicable from July 2021 onwards).

More information on the CE marking can be found here or in the "Blue Guide" on the implementation of EU product rules by the European Commission.

[1] In addition to the 27 EU member states, the EU single market extends to Iceland, Liechtenstein, Norway, and Switzerland.

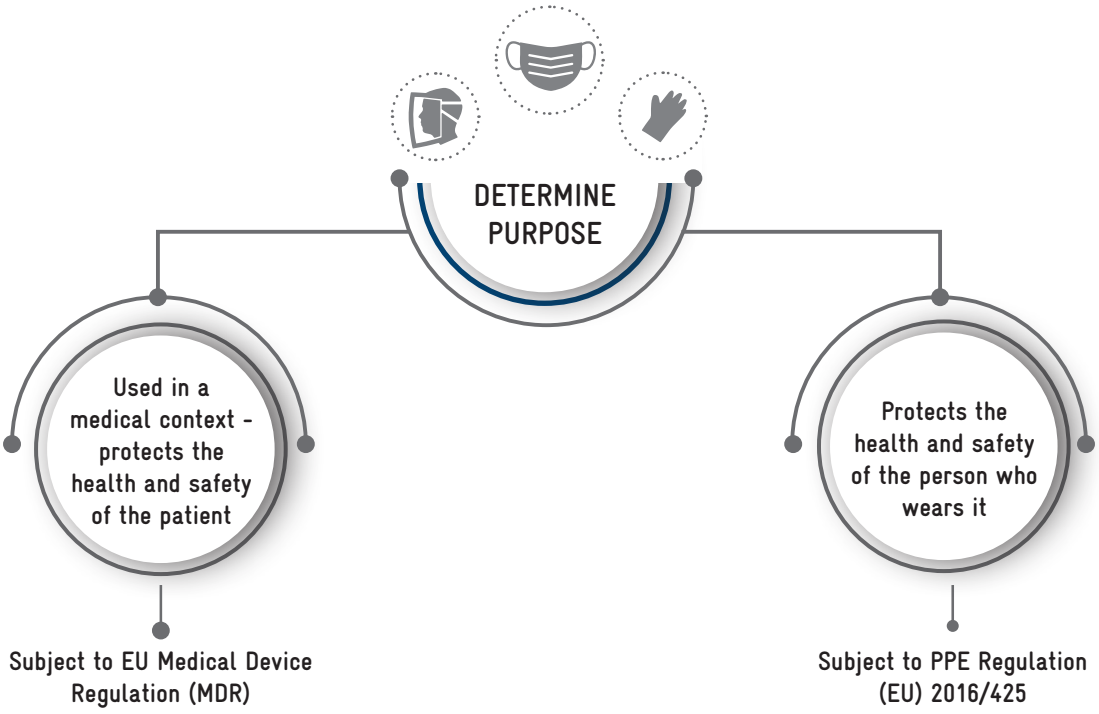
THE CE MARKING OF PPE

The relevant legal requirements and conformity assessment procedures for PPE are outlined in Regulation (EU) 2016/425 (PPE Regulation). It covers the design, manufacturing, and marketing of personal protective equipment. The PPE Regulation is valid for all types of PPE, such as protective masks, protective glasses, face shields, protective gloves and garments. There is an important differentiation between PPE and medical devices in the EU context, as outlined below.

Differentiation between PPE and Medical Products

From a regulatory perspective, it is necessary to differentiate between PPE and medical devices. The differentiation has implications for conformity assessment and certification. The classification is determined by the intended use of a product. If the product's purpose is the use in a medical context – with the intend of protecting the health or safety of a patient – it is considered a medical device and thus subject to the EU Medical Devices Regulation (MDR). By contrast, products whose purpose is the protection of the user, are considered PPE and fall under the PPE Regulation.

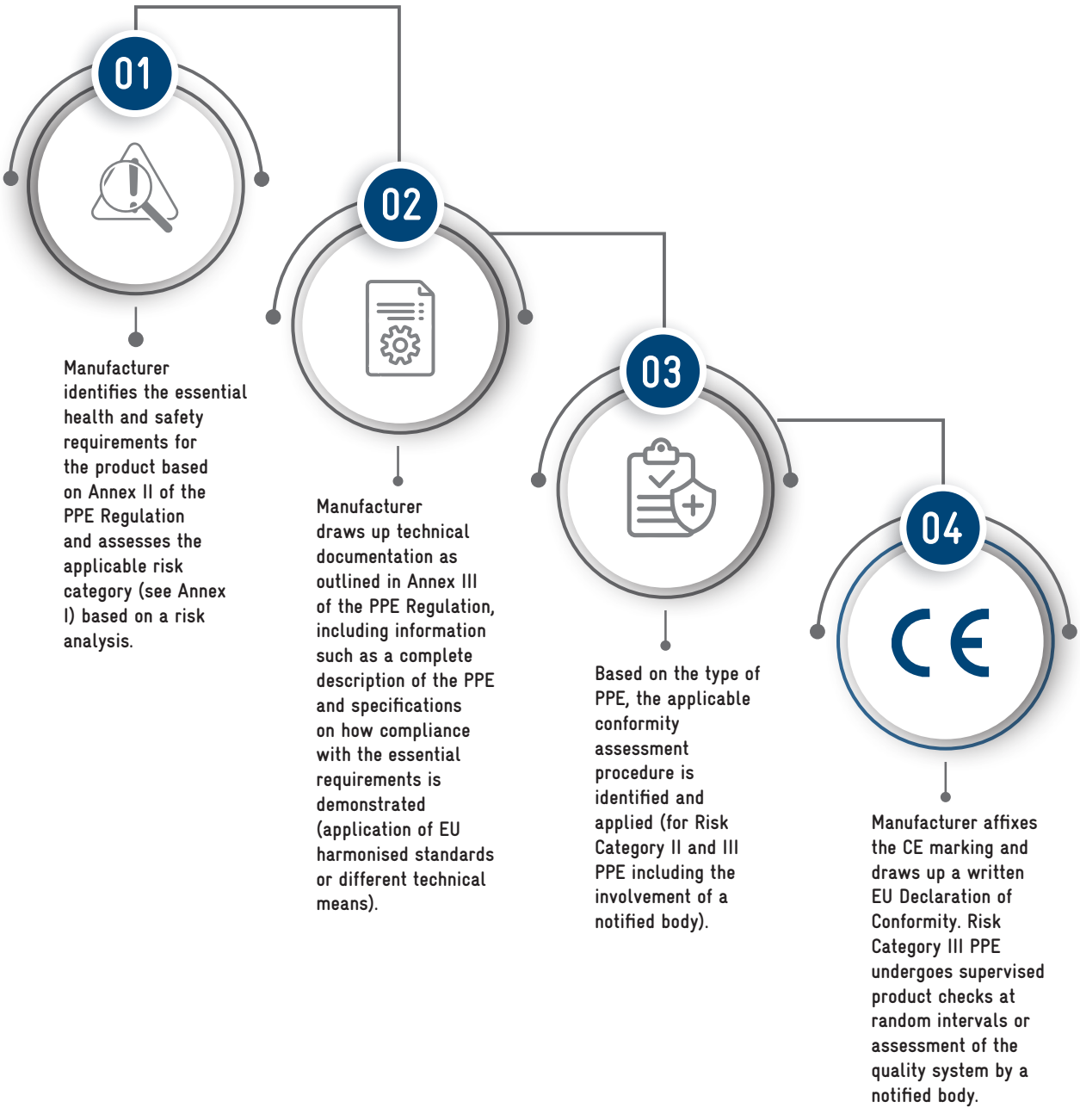
Medical face masks, such as those worn by hospital workers, for example, are marketed as medical devices and thus fall under the MDR. Filtering half-masks (FFP) are intended to protect the wearer of the mask from particles and aerosols and must therefore comply with the PPE Regulation (EU) 2016/425.



The essential health and safety requirements which PPE must fulfil in order to be placed on the EU single market are outlined in Annex II of the PPE Regulation. In line with the New Legislative Framework of the EU, the PPE Regulation outlines the essential health and safety requirements but does not define specific mandatory technical solutions to meet these requirements. One way of complying with the essential requirements is to apply voluntarily harmonised standards. Using harmonised standards has the benefit of a presumption of conformity, leading for example to simpler documentation. The decision whether to apply harmonised standards or to use different means to demonstrate compliance with the essential requirements lies with the manufacturer.

An overview of harmonised European standards under the PPE Regulation is available here.

Key Steps in the Certification Process of PPE



Conformity Assessment Procedures according to the PPE Regulation

PPE are classified in three different risk categories (Risk Category I, II or III) (see Annex I). The conformity assessment procedures to be followed for each of the risk categories are outlined below. It lies in the responsibility of the manufacturers to check if other EU legislation is simultaneously applicable to the product (e.g. REACH[2]).

	Conformity Assessment Module(s)	Involvement of Notified Body	Information
RISK CATEGORY I	A: Internal Production Control	No	Annex IV
RISK CATEGORY II	B: EU type-examination followed by	Yes	Annex V
	C: Conformity to type based on internal production control	No	Annex VI
RISK CATEGORY III	B: EU type-examination followed by	Yes	Annex V
	C2: Conformity to type based on internal production control plus annually surveillance with product checks or	Yes	Annex VII
	D: Conformity to type based on quality assurance of the production process	Yes	Annex VIII

Involvement of Notified Bodies in the Conformity Assessment Procedure

Notified bodies are independent third-party conformity assessment bodies. They are designated by an EU member state to assess the conformity of certain products before they are being placed on the market.

Manufacturers are free to choose any notified body with the required designation and product scope. However, conformity assessment according to the applicable procedures lies in the responsibility of the manufacturer, whether a notified body is involved or not.

According to the conformity assessment procedures, for Risk Category II and Risk Category III PPE, a model/type of the PPE has to be submitted for an EU type-examination before serial production starts, involving a notified body for the type-examination assessment and the issuing of an EU type-examination certificate.

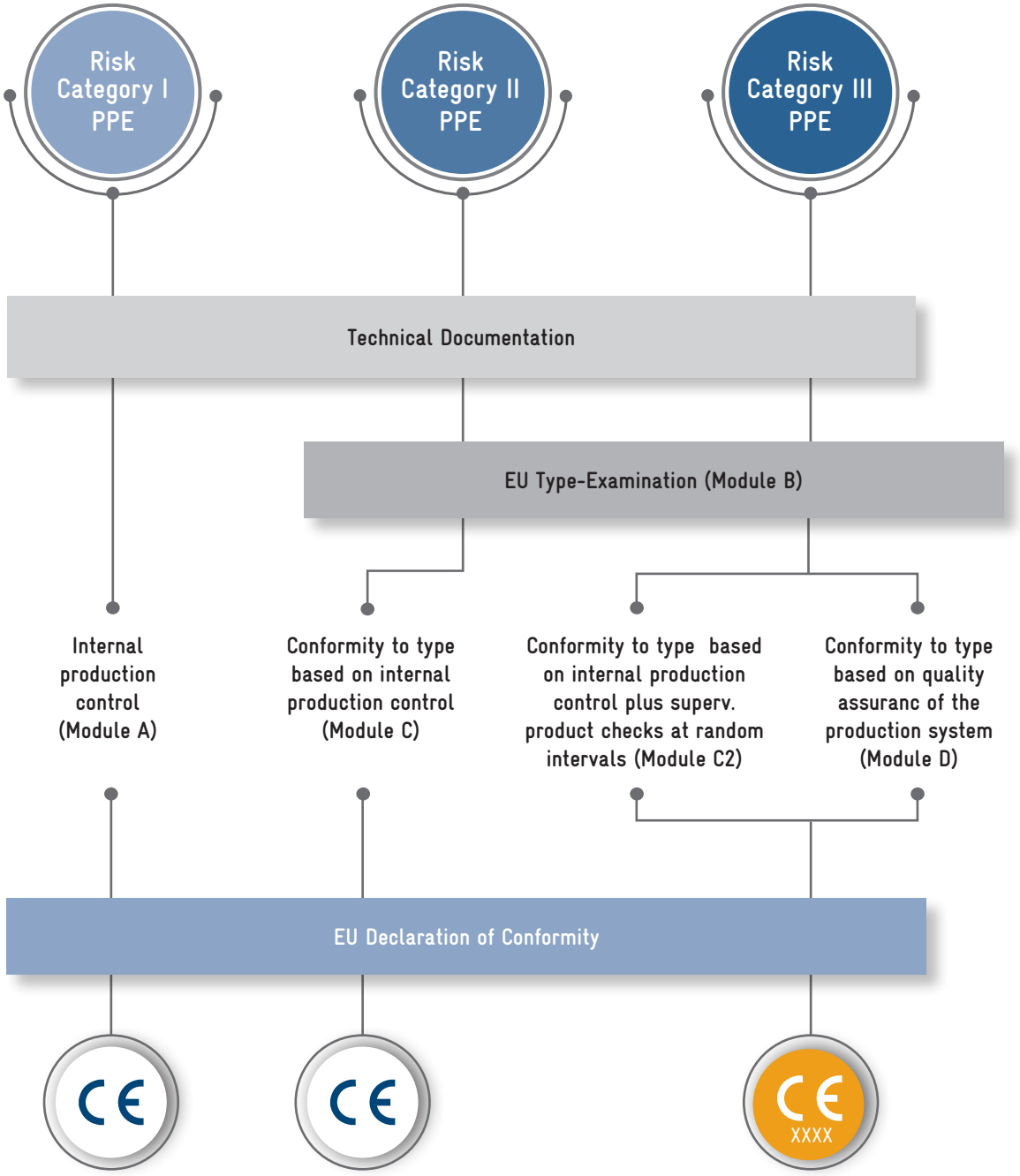
For Risk Category III PPE, before placing on the market, the manufacturer shall apply to a notified body to perform supervised product checks at random intervals or for assessment of their quality system.

A certificate under EU legislation (e.g. an EU type-examination certificate or a quality management system certificate) is issued by a notified body after the applicable conformity assessment procedure has been successfully completed. It is important to note that notified bodies are designated for a specific scope only. Based on their scope they perform specific conformity assessment procedures and issue certificates for specific types of products or quality management systems under specific EU legislative acts.

[2]REACH is the European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals

Affixing of the CE Marking

Once a product has successfully undergone the required conformity assessment procedure, the CE marking has to be affixed by the manufacturer. In case of Risk Category III products, the CE marking is followed by the number of the notified body responsible for the surveillance according to module C2 or D.



Source: Graphic based on PPE Regulation Guidelines, European Commission

The PPE Regulation Guidelines by the European Commission provide support in understanding and implementing the PPE Regulation.

Key questions on the conformity assessment procedures for personal protective equipment are addressed here.

A list of notified bodies under the PPE Regulation is available here.

An overview of harmonised European standards under the PPE Regulation is available here.

ASSESSING THE AUTHENTICITY OF CE MARKING OF PPE

In light of the COVID-19 pandemic, the need and demand for certain PPE has increased significantly globally. As a result, many companies as well as authorities are currently involved in the manufacturing or procurement of PPE without any previous experience in the supply and verification of these products.

In the EU, the safety and compliance of products is ensured based on a system of post market surveillance. Market surveillance authorities identify and take action against products which do not meet the legislative requirements. This surveillance mechanism however only applies to products which are made available on the EU market.

The following part provides practical tips and guidance on how to check the authenticity and validity of CE marking and respective certificates for foreign procurement bodies.

Key Steps in Checking the Authenticity of CE Marking

EU Declaration of Conformity

The EU Declaration of Conformity must be provided and signed by the manufacturer. It must include at least the minimum contents outlined in Annex IX of the PPE Regulation.

Certificate

For PPE of Risk Categories II and III, an EU Type Examination Certificate issued by a competent notified body must be included. It is advised to check the certificate for this exact wording in English or any other EU language. The terms verification of compliance, certificate or certification report are not correct legal terms and are an indication for a misleading certificate.

The certificate must specify the conformity assessment procedure applied and include the name and 4-digit identification number (NB xxxx) of the issuing notified body. If these specifications are missing or the notified body mentioned is located outside the EU, this is an indication for a misleading certificate since notified bodies for PPE are all based in EU member states or Norway, Switzerland and Turkey.

To check if the notified body indicated on the certificate is genuine and notified/competent for PPE, the Nando database of the EU can be consulted. Not all notified bodies for PPE are competent for all types of PPE. The Nando database includes information on all notified bodies for PPE as well as their scope. It is possible to search for the number or name of a notified body directly in the database. It is also possible to filter according to procedure or product type.

Some of the issuing notified bodies offer the possibility to check the validity of their documents on their website directly. However, a valid document in their view is not necessarily a valid EU Type Examination Certificate. To assess the authenticity, it can also be helpful to critically examine the visual characteristics of the certificate.

Checklist

Is the issuing organisation a genuine notified body?

Go to Nando database

Search for identification number/name

Is the issuing organisation a notified body competent for PPE?

Go to Nando database for PPE Regulation

Check list of notified bodies

Is the issuing notified body competent/notified for the right type of PPE?

Go to Nando database for PPE Regulation

Filter according to product type

More information by the European Commission on how to verify that personal protective equipment can be lawfully placed on the EU market can be found here.

More information on suspicious PPE certificates can also be found on the website of the European Safety Federation (ESF) here.

Sources

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About GPQI

The Global Project Quality Infrastructure (GPQI) of the German Federal Ministry for Economic Affairs and Energy (BMWi) engages in technical and political dialogues with Brazil, China, India, Indonesia, and Mexico to reduce technical barriers to trade, enhance product safety, and strengthen consumer protection. GPQI serves as a platform to improve the mutual understanding of policies and regulations, and to jointly develop positions and solutions for international technical harmonisation. Common bilateral interests are the basis for the cooperation on challenges and opportunities on standardisation, conformity assessment and accreditation, legal metrology, and market surveillance with a wide range of stakeholders. These include ministries, regulators, public agencies, standards and accreditation bodies, industry experts, associations, companies, and technical and scientific institutions. BMWi has commissioned the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH – the German Agency for International Cooperation – to support the implementation of GPQI. The project coordinates stakeholder inputs on draft regulations and standards, expert exchanges, delegation visits, and sectoral cooperation, and releases technical publications.

For more information visit www.gpqi.org.

Deutsche Gesellschaft für
Internationale Zusammenarbeit (GIZ) GmbH

Sitz der Gesellschaft
Bonn und Eschborn

Friedrich-Ebert-Allee 36 + 40
53113 Bonn, Deutschland
T +49 228 44 60-0
F +49 228 44 60-17 66

Dag-Hammarskjöld-Weg 1 – 5
65760 Eschborn, Deutschland
T +49 61 96 79-0
F +49 61 96 79-11 15

E info@giz.de
I www.giz.de