

2025 June

INTRODUCTION

The aim of this document is to inform about the responsibilities of anyone (importer) putting onto the EU market equipment, machinery and material requiring CE marking.

These recommendations and obligations are an abstract of the **2022 Blue Guide on the implementation of the product rules published by the European commission.**

The Blue Guide is meant for a better understanding of EU product rules and facilitation of their uniform application across sectors throughout the Single Market. It also provides explanations and advice regarding the European conformity assessment system, the accreditation of laboratories, the CE marking, and market surveillance.

https://single-market-economy.ec.europa.eu/news/blue-guide-implementation-product-rules-2022-published-2022-06-29_en

PRODUCTS IMPORTED FROM COUNTRIES OUTSIDE THE EU

Irrespective of their origin, products must be compliant with the applicable Union harmonization legislation when placed on the market.

The basic principle of EU product rules is that irrespective of the origins of the products, they need to be compliant with the applicable Union harmonization legislation when placed on the market. Products manufactured in the EU and products from non EU countries are treated alike.

For products imported from countries outside the EU, Union harmonization legislation envisages a special role for the importer.

The latter assumes certain obligations which to some extent mirror the obligations of manufacturers based within the EU.

IMPORTER

- *The importer is a natural or legal person established in the Union who places a product from a third country on the EU market.*
- *His obligations build on the obligation of the manufacturer.*

The importer is the economic operator established in the Union who places a product from a third country on the Union market.

He has important and clearly defined responsibilities under Union harmonization legislation. To a large extent they build on the type of responsibilities which a manufacturer based in the EU is subjected to.

The importer must ensure that the manufacturer has correctly fulfilled his obligations. The importer is not a simple re-seller of products, but has a key role to play in guaranteeing the compliance of imported products.

The importer is defined as any natural or legal person who places a product from a third country on the EU market. As a general rule, before placing a product on the market the importer must ensure:

1. That the appropriate conformity assessment procedure has been carried out by the manufacturer. If he has any doubt about the conformity of the product, he must refrain from placing it on the market. If the product has already been placed on the market, he has to take corrective actions. In both cases the manufacturer might need to be contacted to clarify any doubt about the conformity of the product.
2. That the manufacturer has drawn up the technical documentation, affixed the relevant conformity marking (e.g. CE marking), fulfilled his traceability obligations and accompanied, where relevant, the product by the instructions and safety information in a language easily understood by consumers and other end-users, as determined by the Member State concerned

These obligations are meant to make sure that the importers are aware of their responsibility to place only compliant products on the market. Neither do they imply the need for importers to systematically resort to additional control procedures or (third party) testing, nor do they preclude them from doing so.

The importer also has to:

Indicate the following two elements: his name, registered trade name or trademark and the address at which he can be contacted on the product or where not possible because of the size or physical characteristics of the product or because the packaging would need to be opened, on the packaging or/and on the accompanying documentation. By doing so, he must not impede the visibility of any safety information printed on the product or the accompanying documents.

- Ensure that, while a product is under his responsibility, storage or transport conditions do not jeopardize its compliance with the requirements set out in the applicable legislation.
- Keep a copy of the EU Declaration of Conformity for 10 years after the product has been placed on the market or for the period specified in the relevant Union harmonization act.
- Ensure that the technical documentation can be made available to the competent national authority upon request. The importer must cooperate with that authority and upon a reasoned request, has to provide that authority with all the information and documentation necessary to demonstrate the conformity of the product in a language which can be easily understood by that authority. The idea is that the national authority might accept a language they understand, and which is different from the national language(s). The language chosen is subject to negotiation with the authority and could be a third language, if accepted by the authority.
- In the case of a reasonable request it is sufficient for the importer to provide the part of the technical documentation related to the claimed non-conformity and appropriate for demonstrating whether the issue has been dealt with by the manufacturer. Therefore, any request for translation of technical documentation should be limited to these parts of the documentation.

- On request by market surveillance authorities, the importer must identify any economic operator who has supplied him and to whom he has supplied the product. He must be able to present this information for a period of 10 years after he has been supplied with the product and for a period of 10 years after he has supplied the product.

Further, under certain Union harmonization acts, the importer, like a manufacturer, may be required to perform or have performed sample testing of products already placed on the market.

Equally, importers who have reason to believe that a product which they have placed on the market is not in conformity with the Union harmonization legislation applicable, shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate.

Furthermore, where the product presents a risk, importers shall immediately inform the competent national authorities.

The importer needs neither a mandate from the manufacturer, nor a preferential relationship with the manufacturer like the authorized representative. However, the importer must ensure, in order to fulfil his responsibilities, that a contact with the manufacturer can be established (e.g. to make the technical documentation available to the requesting authority).

The importer may wish to carry out administrative tasks on behalf of the manufacturer. In such a case, he must be explicitly designated by the manufacturer to become an authorised representative.