

The obligations for economic operators in accordance with the common framework for the marketing of products in the EU (extract from Decision no. 768/2008/EC)

Definitions:

- **Economic operators:** The manufacturer, the authorised representative, the importer and the distributor.
- **Manufacturer:** any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.
- **Authorised representative:** any natural or legal person established within the community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.
- **Importer:** any natural or legal person established within the community who places a product from a third country on the community market.
- **Distributor:** any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

Obligations:

- **Manufacturers:**
 1. When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in the relevant part of the legislation.
 2. Manufacturers shall draw up the required technical documentation and carry out the conformity assessment procedure applicable or have it carried out. – Where compliance of a product with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity and affix the conformity marking.
 3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period specified in proportion to the lifecycle of the product and the level of risk, after the product has been placed on the market.
 4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specification by reference to which conformity of a product is declared shall be adequately taken into account. – When deemed appropriate with regard to the risk presented by a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.
 5. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.
 6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.
 7. Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

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8. Manufacturers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the applicable Community harmonisation legislation shall immediately take the necessary corrective measures to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, given details, in particular, of the non-compliance and of any corrective measures taken.
 9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it 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. They shall cooperate with that authority, at its request, on any action taken to eliminate the risk posed by products which they have placed on the market.
- **Authorised representatives:**
 1. A manufacturer may, by a written mandate, appoint an authorised representative. The obligation in the above manufacturer's obligations point 1 shall not form part of the authorised representative's mandate.
 2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
 - Keep the EC declaration of conformity and the technical documentation at disposal of national surveillance authorities for a period specified in proportion to the lifecycle of the product and the level of risk.
 - Further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product.
 - Cooperate with the competent national authorities, at their request, on any action taken to eliminate the risk posed by products covered by their mandate.
 - **Importers**
 1. Before placing a product on the market importers shall ensure that manufacturers has complied with the above manufacturers obligations point 1-6. – Where an importer considers or has reason to believe that a product is not in conformity with relevant part of the legislation, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.
 2. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where it is not possible, on its packaging or in a document accompanying the product.
 3. Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.
 4. Importers shall ensure that, while a product is under their responsibility, storage and transport conditions do not jeopardise its compliance with the requirements set out in the relevant part of the legislation.
 5. When deemed appropriate with regards to the risk presented by a product, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and recalls, and shall keep distributors informed of such monitoring.

6. Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the Community harmonisation 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 of the Member State in which they made the product available to that effect, given details, in particular, of the non-compliance and of any corrective measures taken.
7. Importers shall for a period specified in proportion to the lifecycle of the product and the level of risk, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.
8. Importers shall further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

- **Distributors:**

1. Before placing a product on the market distributors shall ensure that importers has complied with the above importers obligations point 1-3. – Where a distributor considers or has reason to believe that a product is not in conformity with relevant part of the legislation, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the importer shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities
2. Distributors shall ensure that, while a product is under their responsibility, storage and transport conditions do not jeopardise its compliance with the requirements set out in the relevant part of the legislation.
3. Distributors who consider or have reason to believe that a product which they have placed on the market is not in conformity with the Community harmonisation 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 of the Member State in which they made the product available to that effect, given details, in particular, of the non-compliance and of any corrective measures taken.
4. Distributors shall further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.