Authorized Representative Service

@QIMA Europe AR GmbH

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Reference and definition

Manufacturers, whether they are based inside or outside the European Union (EU), may appoint an authorized representative (AR) in the EU to carry out certain tasks on their behalf

QIMA Europe AR GmbH is established in Germany (member of the EU)

Reference

Under regulation 2019/1020/EU, from 16th of July 2021, products with CE marking can no longer be sold in EU without an AR established in the EU

EC REP

Definition

AR means any natural or legal person established within the EU who has received a **written mandate from a manufacturer to act on its behalf in relation to** manufacturer's obligations under the relevant harmonized legislation, regulation or directives

Applicable Area – Countries in the EU and EEA

EU countries include:

Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden

The European Economic Area (EEA)

The EEA includes EU countries and also Iceland, Liechtenstein and Norway. It allows them to be part of the EU's single market

Switzerland is not an EU or EEA member but is part of the single market

CE marking requirements

- CE marking:
  - Indicates a product has been assessed by the manufacturer
  - Product is deemed to meet EU safety, health and environmental protection requirements
  - Required for products manufactured worldwide who are selling in the EU
  - Only obligatory for products where EU specifications exist and require the affixing of CE marking
- Some products are subject to several EU requirements
- Manufacturers must make sure that their product complies with all the relevant requirements
- It is forbidden to affix the CE marking to products where EU specifications do not exist or do not require the affixing of CE marking
- The CE marking must be visible, legible and indelible

CE marking requirements

How to obtain CE marking?

- Product's manufacturers bear sole responsibility for declaring conformity with all requirements. They don't need a license to affix the CE marking, however, they must:
  - Ensure conformity with all relevant EU-wide requirements
  - Determine whether they can assess their product by themselves or if they need to involve a notified body
  - Put together a technical dossier documenting conformity: find out about technical documentation
  - Draft and sign an EU declaration of conformity
- Upon national authority’s request, manufacturers must provide information and supporting documentation concerning CE marking

Product categories under AR Service

CE-marked products (except for medical devices, explosives for civil uses, and certain lifts and cableway installations):

Materials and articles in contact with food

Personal protective equipment (PPE)

Toys

Children's products (e.g., cribs, furniture)

Measuring instruments

Machines

Power tools, handheld tools

Hardgoods (e.g., furniture, sporting equipment, sunglasses)

E-Mobility (e.g., pedelec, cargo-bikes, scooter)

Ecologically designed energy products

Electrical and electronic equipment, appliances, or products

Products subject to the Electromagnetic Compatibility Directive

Radio telecommunications equipment

Products subject to the Construction Products Regulation (CPR)

Responsibilities of EU AR

What's required for the AR

- Provide an EU contact address for the product, packaging, and documentation
- Confirm that clients have completed required assessments, certifications and registrations
- Review clients' technical documentation to make sure it meets requirements
- Verify that product labeling (CE marking) and traceability references are correct
- Hold technical documentation and declaration of conformity as required (10 years)
- Work with surveillance authorities on clients' behalf, providing documentation on request and reporting compliance incidents

Specific explanation – labeling

- Once the document check is completed and all documents are available and valid, EU AR will confirm that the client is allowed to use their address on the label

- As shown below:

EC REP

Manufacturer:

Name
Full address
Contact number / E-Mail

Authorized representative:

QIMA Europe AR GmbH
Schleidenstraße 1
22083 Hamburg
GERMANY

Risk for manufacturers and suppliers without an established AR

- Possible consequences if you use an AR who does not check your documents:
  - Prohibit to import the goods into the European Union
  - Penalties for wrong labeling and missing information in instruction manuals
  - Potential product-recall if the product does not comply with European Directives

Required documents from manufacturers and suppliers

- The technical documentation should include at least:
  - Business registration
  - Company name and address, or those of any AR
  - A brief description of the product
  - Identification of the product, for example, the product's serial number
  - The name(s) and address(es) of the facilities involved in the design and manufacture of the product
  - The name and address of any notified body involved in assessing the conformity of the product
  - A statement of the conformity assessment procedure that has been followed
  - The EU declaration of conformity (DoC)
  - Label and instructions of use
  - A statement of relevant regulations to which the product complies
  - Identification of technical standards with which compliance is claimed

All documents need to be in English and the language of the destination

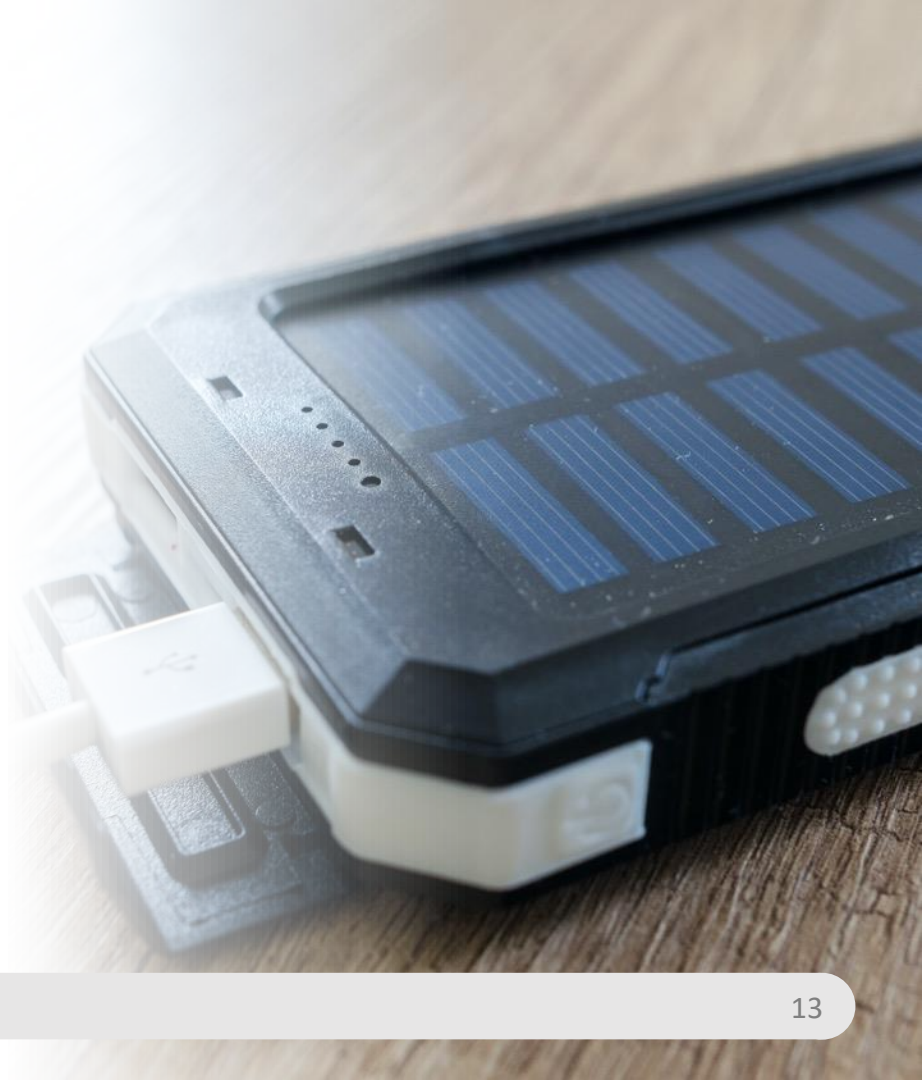
EU Declaration of Conformity (DoC)

- An EU DoC is a mandatory document manufacturers need to sign to declare product compliance with EU requirements
- It should contain the following information:
  - Company name and address or that of their authorized representative
  - The product's serial number, model or type identification
  - A statement, stating they take full responsibility
  - Means of identification of product allowing traceability – this can include an image
  - The details of the notified body which carried out the conformity assessment procedure (if applicable)
  - The relevant legislation with which the product complies, as well as any harmonized standards or other means used to prove compliance
  - Their name and signature
  - The date the declaration was issued
  - Supplementary information (if applicable)

EU declaration of conformity must be translated into the language or languages required by the EU country in which their products are sold

Case Study 1

- Company: Electrical and electronic company
- Products: Powerbank with additional function
- Scenario: Manufacturer failed to put a WEEE mark on the product and failed to register their product, so the product does not comply with German ElektroG
- Possible penalty up to 50.000 EUR



Case Study 2

- Company: Electrical and electronic company
- Products: Bluetooth Headphones
- Scenario: Product was CE marked and authority asked for documentation. Manufacturer and AR were unable to provide the proper declaration of conformity and the technical documentation

> (a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity or declaration of performance and technical documentation, verifying that the EU declaration of conformity or declaration of performance and technical documentation have been drawn up, keeping the declaration of conformity or declaration of performance at the disposal of market surveillance authorities for the period required by that legislation and ensuring that the technical documentation can be made available to those authorities upon request;

- Penalty: AR could be punished. Even the manufacturer could be punished up to 50,000 EUR (for missing CE mark) and up to 25,000 EUR for missing information

The QIMA Benefits

We protect your confidentiality by keeping design and manufacture documentation out of the hands of importers/distributors

We act in your best interest when decisions may need to go against the interests of an importer/distributor

We respond to requests from authorities promptly and effectively while distributors and company branch offices may have other priorities

We offer expertise in quality and compliance across multiple markets, ensuring that you receive quality advice and support throughout the process

Email: info@qima.com
Visit: www.qima.com

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