13th April 2021

Economic Operators for CE-marked Products in the EU

Authorised Representatives

It is possible to meet some of the regulatory requirements for CE marking through use of an Authorised Representative (AR) and for some product types, such as medical devices, these are mandatory where the Manufacturer is not EU-based. While the UK was an EU member state there has been no great incentive to appoint an AR for products manufactured by BEAMA members. Even after the end of Brexit Transition, it has not been essential since it is entirely acceptable for a non-EU Manufacturer to CE mark products, make and sign the Declaration of Conformity (DoC) or Declaration of Performance (DoP), compile the Technical File to prove regulatory and standards conformity, and supply the product to EU end-customers without there being any other parties with regulatory responsibilities.

A complication does arise with non-EU membership in that customers in the EU (and Northern Ireland) who would have been Distributors before are now likely to be classed as Importers and so will have greater obligations to check that there is a DoC for a CE marked product and that the Manufacturer has carried out the other obligations to compile the Technical File. Members may already have been requested to nominate an AR in the EU or otherwise add an EU-based name and address to the product in an attempt by Distributors to bypass these obligations. Even where this has been done, it does not remove the obligations of those companies that are now Importers to carry out due diligence on their CE marked products. Where the product is imported by the end-customer, no further obligations have applied as end-users are under no legal obligations with regard to regulatory conformity of products purchased.

The change arises when EU Regulation 2019/1020 on market surveillance and compliance of products (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32019R1020) comes into force on **16th July 2021**. This contains a variety of changes to the obligations of 'economic operators' with regard to CE marked products, mainly to include fulfilment service providers such as Amazon as having obligations towards market surveillance authorities in the EU. The other change is that it requires that a CE marked product can only be placed on the EU market if there is an economic operator 'established in the EU' who is responsible for:

- Verifying that a DoC/DoP and Technical File have been drawn up
- Keeping the DoC/DoP at the disposal of market surveillance authorities and ensuring the Technical File can be made available
- Providing market surveillance authorities with information regarding conformity of the product when requested, informing them if there is reason to believe the product presents a risk and cooperating with any corrective or mitigating action with regard to product risks.

If you are a non-EU Manufacturer, there will therefore need to be somebody who is established in the EU who will undertake those responsibilities and have their name and postal address on the product, packaging, parcel or an accompanying document.

Guidelines for economic operators on the practical implementation of this Regulation has also been published at https://ec.europa.eu/docsroom/documents/44908

Options

1. **Importer Responsibility**

Importers already have responsibility for verifying that there is a valid DoC/DoP and Technical File, as well as being required to have name and address on or with the product so in principle it is not a great extra step for them to be the responsible economic operator. However, many distributor/importers will resist any additional responsibilities so this may be challenging to establish. Some UK distributor companies who supply into Ireland or other EU member states are already taking steps to avoid being deemed the Importer of UK/GB products for the purposes of EU Reg 2019/1020

2. **Customer Responsibility**

The EU Commission Guidelines clearly state that for products shipped from outside the EU directly to an end-user in the EU, if the Manufacturer has not appointed an AR, the product may not be offered for sale to EU end-users. The end-user customer will not become an Importer and the non-EU Manufacturer must appoint an AR.

3. **Multinational Groups**

If you are part of a corporate group of companies including one or more based in an EU member state, then having the registered name and address of an EU sister/parent company on the product documentation will usually suffice, even if it is one of a list of associated companies on an instruction leaflet. This documentation does not need to state whether the EU sister company is to be treated as the Importer or the Authorised Representative, although you would need to ensure that any company that might be approached by Market Surveillance is aware of the possibility, has a record of their appointment as AR (the Mandate) and can access the DoC/DoP and Technical File in case of a request.

4. **Authorised Representative**

You can appoint an AR to carry out these responsibilities, the delegation of such tasks must be in writing and must include:

- Keeping the DoC/DoP and Technical File at the disposal of Market Surveillance authorities
- Providing on request all documentation to demonstrate conformity
- Cooperating with national authorities on any action to eliminate product risks, e.g. recalls.

The AR can be an individual or a company but must be 'established in the EU'. Although this term is not defined by the Regs, other precedents suggest it requires either being a company registered in an EU member state or having a permanent address in an EU member state. The 'permanent

address' does require regular, if not full-time occupation but specific requirements to prove an individual's residency will vary between member states. It would not be sufficient for a UK/GB company to simply use a PO Box number or similar 'virtual' presence.

It would be possible for a UK/GB company to form a registered company in an EU member state as their AR but this would need to be in accordance with the national company law in that state. This will generally require a local registered address, constitutional documents including Directors' details, annual returns and fees to be paid. Some states may require at least one Director to be a national of the country in question or of the EU.

The AR's responsibilities are clearly stated to be administrative in nature so the fact that a product's declaration or technical documentation proves to be faulty would not imply any liability for those deficiencies.

Whichever type of AR is chosen, their name and postal address must be supplied on the product, packaging or accompanying documentation. For the directives on Machinery, Construction Products and Outdoor Noise, any AR contact details must be on the DoC/DoP.

5. Fulfilment Service Providers

Providers of fulfilment services such as warehousing, packaging, addressing and dispatching are also caught by the new Regulation if there is no EU Manufacturer, Importer or AR. Amazon and similar operations will therefore need to obtain DoCs and have access to Technical Files from non-EU Manufacturers in the absence of an Importer or AR so might be expected to require sellers to put an AR arrangement to be in place.

Actions for BEAMA Members

1. Multinational Groups

The UK company in a multinational group that has operations in the EU and sells under a unified brand will have the options to:

a. deem a sister EU company to be the Manufacturer, with UK manufacturing viewed as being under subcontract. This will mean that the EU company will have the Manufacturer's compliance obligations, which are considerably more onerous than an Importer or AR; or
b. deem a sister EU company to be the Importer. Either option a. or b. might involve additional administrative requirements for invoicing, taxation etc.
c. appoint a sister EU company as AR, as long as the required formalities are in place.

2. UK/GB-only Companies

For sales into the EU of CE-marked products, either:

a. an AR will need to be appointed, given a mandate and their contact details included with the product; or

b. an intermediate operator taking the product into the EU and selling it on will be the Importer and will need to obtain the DoC and add contact details; or
c. a sale through a fulfilment centre will mean the provider will need to carry out the DoC and contact information requirements.

Northern Ireland

As in other areas, the Northern Ireland (NI) Protocol to the UK/EU Withdrawal Agreement adds a further complication but may also give help to some UK companies.

Goods supplied into Northern Ireland from Great Britain (GB) will need to have CE marking even after UKCA marking becomes fully mandatory in GB. This means that the requirements of EU Reg 2019/1020 will also apply, therefore a GB Manufacturer will need to ensure that any current NI distributor will become the Importer or else appoint an NI or EU Authorised Representative. Either an NI Importer or AR will need to meet the requirements for DoCs and adding contact details.

For companies that already have, or can easily set up an NI operation of some kind, such as a sales office, this could be used for the purpose of appointing an AR. If this route is taken for NI sales of CE-marked products, it would also meet requirement for other sales into the EU single market, which for these purposes includes the EEA states of Norway, Iceland and Lichtenstein.

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