The LANGUAGE Center
The One Source for a World of Translation Services

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CE Marking for European Directives

European Regulatory Language Requirements

CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislations, in practice by many of the so-called Product Directives which contain the "essential requirements" and/or "performance levels" and "Harmonized Standards" to which the products must conform. What this in essence means for the manufacturer is that CE Marking is essentially a passport to Europe allowing manufacturers to freely circulate their products within the European market. In labeling a product for sale under the CE mark, guidance for language requirements must be sought from the appointed Competent Authority within each country. These standards typically differ depending upon the end-user, as well as whether the product is intended for professional or for consumer use. If the expectation is that the professional has a good understanding of English or another EU standard language, the requirements for translation are lessened. However, if the product is intended for use by consumers, then the requirements may differ significantly and in fact often require adherence to specific languages depending upon the individual member state which may include translation into one or even more national or local languages.

Failure to comply with language requirements for each country can provoke a response by a regulatory body and be instigated by something as simple as a complaint or any of the following: unhappy customers, random checks by the government, or accident investigators. Also, failure to include a translation in a particular language may require the company to clarify and explain its decision not to translate to the regulatory body. The stipulation that the product is for professional use only requires application to the Competent Authority to be exempt from translation into local languages which may require additional time and expense.

European Languages as a Regulatory Requirement

In the medical field, different categories of medical products fall under different classifications and different European directives (MDD/IVDD/AIMDD). Essential to the translation and localization process in this specific industry, a project must be carried out in the most precise and professional way. This is especially true due to the very nature of the products themselves, and indeed in many cases the products use may be

intended for invasive procedures, which necessarily elevate the risk factor. The European language requirements are intended to ensure that each user in each Member State will be able to correctly use medical devices which are being imported into Europe.

The Medical Device Directive (MDD 93/42/EEC), in effect since June 14, 1998, requires non-European medical device manufactures to acquire CE-Marking by complying with the Medical Device Directive. Any non-European medical device manufacturer whose product does not bear the CE-Mark will not be able to market the product in Europe or in any other country which requires CE-Marking as a quality mark. Regarding the language requirement, the **MDD clearly states in Article 4.4, Annex I, 13.3** the following: “Member States may require the information, which must be made available to the user and the patient in accordance with Annex I, Point 13, to be in their national language(s) or in another community language, when a device reaches the final user, regardless of whether it is for professional or other use.”

The In Vitro Diagnostic Directive (IVDD 98/79/EC) published October 7, 1998 requires all non-European IVD manufacturers to obtain CE-Marking in order to circulate/sell/move their products within the EU territory. The IVD Directive points out the right of each Member State to demand products being distributed in their country to be distributed in their local language(s). Annex I.B, Article 8.4 states that: “Member states may require the information to be supplied pursuant to **Annex I, part B, Section 8** to be in their official language(s) when a device reaches the final user. Provided that safe and correct use of the device is ensured, Member States may authorize the information referred to in the first subparagraph to be in one or more other official community languages.”

The Active Implantable Medical Device Directive (AIMDD 90/385/ EEC) effective June 20, 1990 states that all active implantable medical device manufacturers must acquire CE-Marking to be able to put their products on the European Market. The AIMD 90/385/ EEC also mentions the language requirement issue in Article 4.4 “when a device is put into service, Member States may require the information described **in sections 13, 14 and 15 of Annex I** to be in their national language(s).”

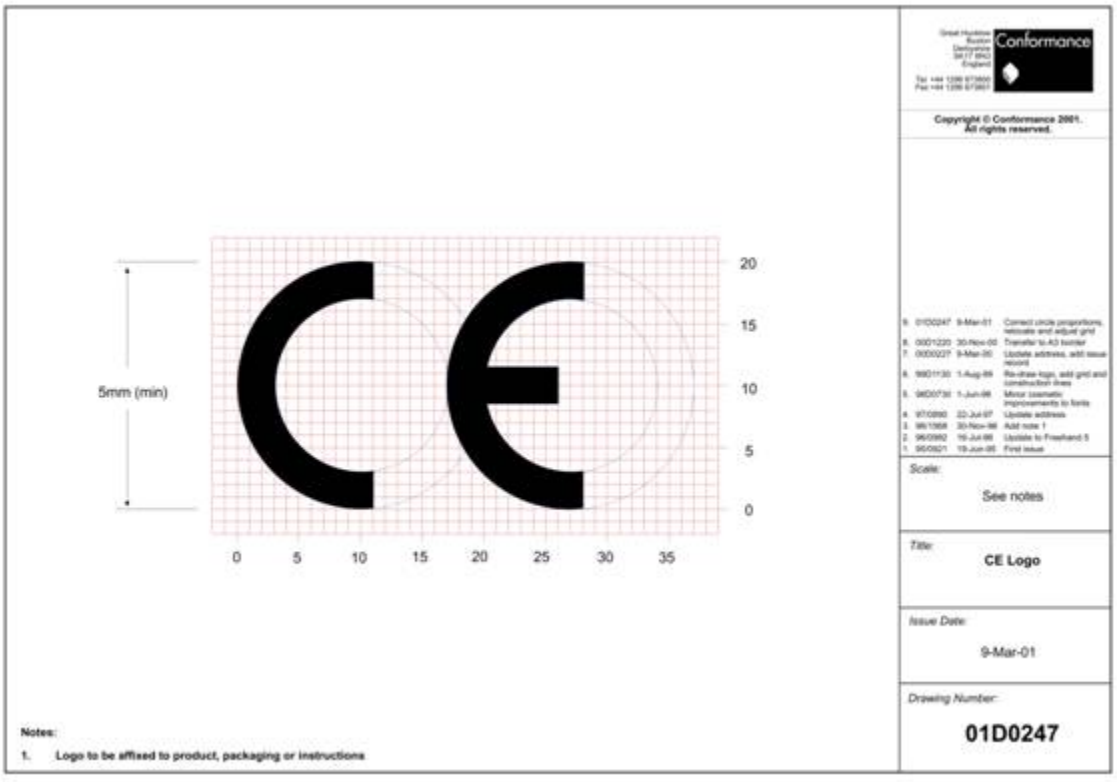
What was the principle guideline of the publication of the MDD 93/42/EEC, IVD 98/79/EC, AIMD 90/385/EEC directives?

The European Union is trying to harmonize all the regulatory differences between each of its Member States. The MDD as well as the IVDD and AIMDD came to create this harmonization and reduce the regulatory complexity of selling non-European products within the European Union. By complying with these directives the manufacturer is able to bear the CE-Marking on its products, instructions for use, labeling and circulating his products freely within the European free trade zone territory (EEA).

CE-Marking: A passport to the European Union

The letters CE are an abbreviation of the French term “conformité européenne.” They indicate that the manufacturer complies with all applicable EEC legal requirements of the EU “New Approach Directives.” There are about 22 Directives that are either already in use or under consideration which demand that the product be marked with the CE-Marking. More than one directive can apply to each product.

As stated previously, CE-Marking is a passport to Europe which allows manufacturers to freely circulate their products within the European market. Until 1985 the European Directives demanded specific and detailed requirements in each product category. The harmonization of standards in the European Union has been pursued for some time and one of its goals is to establish a European free trade zone as well as setting uniform requirements for manufactured products to ensure the necessary level of protection with respect to safety, health, and environment. The standardization has the effect of allowing a freer transfer of goods across the EU as well as to ensure a single standard throughout the EU which allows manufacturers to take advantage of a larger market using a single standard.



Official Language(s) of all 25 EU Member States

Member State	Official Language(s)
Austria	German
Belgium	Dutch, French & German
Cyprus	Greek
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	English
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxembourg	French, German, Luxembourgish
Malta	English & Maltese
Poland	Polish
Portugal	Portuguese
Slovakia	Slovak
Slovenia	Slovenian
Spain	Spanish
Sweden	Swedish
The Netherlands	Dutch
United Kingdom	English

Official Language(s) of EFTA Member States

Member State	Official Language(s)
Iceland	Icelandic
Liechtenstein	German
Norway	Norwegian
Switzerland	German, French, Italian

Language Requirements for European Countries applying to become EU Members

Member State	Official Language(s)
Bulgaria	Bulgarian
FYROM	Albanian
Croatia	Croatian
Romania	Romanian
Turkey	Turkish

In summary, the medical directives MDD/IVDD/AIMDD were created in order to harmonize regulatory requirements within the European Union. One important issue within these directives deals with language requirements in Europe. Although none of the directives clearly mentions which languages apply to each individual Member State, all of the above-mentioned directives affirm that each Member State has the right and the responsibility to ensure that the products which are being distributed within their borders will be done so according to their local language requirements. This ensures safe use by both professional and non-professionals, i.e. trained medical professional as well as the layman. Only a professional translation/localization process, especially when dealing with medical devices, can meet the requirements for both the professional and non-professional users.

Medical translation and localization as a commercial and marketing value

It is understood from the regulatory requirements that translating and localizing your labels and instructions for use will ensure your compliance with the European Medical Directives and allow you to market your products within all 25 EU Member States. But translation and localization also has a commercial/sales/marketing value when penetrating new foreign markets.

What are the localization benefits?

Before the actual benefits are mentioned, it is important to keep in mind that only 14% of the EU market is English speaking. In order to successfully penetrate this market you must convey your message whether it is of a technical or marketing nature in the languages of the target market.

Localization benefits:

- Ensures correct and safe use of your product.
- Increases awareness of the product in the target country.
- Demonstrates respect and understanding of your target audience by communicating your message in their native language thereby increasing the likelihood of success.
- Allows you to more easily compete with local manufacturers.
- Increases customer satisfaction.

Why not use your distributor also as a translator?

Medical translation and localization is a very complex process. It entails several levels of execution and involves several industry specific individuals and professional linguists dedicated to a particular translation project. **Your distributor is neither.** Your distributor distributes several products from several industries which may not have any relation to yours.

Be aware, your distributor cannot be responsible for, or be expected to understand the regulatory requirements involving language within each individual Member State. By using your distributor to translate your technical documentation you are putting your factory, product and brand name at risk because you cannot be sure that the translation of your labeling/instructions for use will meet your needs or EU requirements. Using a professional translation company can ensure that the translations, proof reading and Quality Assurance will be conducted by professionals from the industry and inside the target market you wish to penetrate. **The Language Center** does exactly that and ensures that all your technical related documentation as well as your marketing and sales literature is being translated, proofread and QAed by our experts in the field and managed by our experienced project management staff.

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