info@welocalize.com
800-370-9515

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# A Guide to The IVD Directive

One of the requirements that the In Vitro Diagnostics Directive (IVDD) specifies is that manufacturers' comply with set language standards regarding instructions-for-use documents and labeling. The deadline for compliance is fast approaching, and Welocalize would like to help you successfully meet IVDD language requirements through its professional translators and medical subject matter experts (SMEs).

The IVD Directive, at its core, is purposed to ensure the safety, quality, and performance of In Vitro Diagnostic (IVD) products. It is extremely important for IVD product manufacturers to understand that after December 7, 2003, all IVD products must be CE (Conformity European) marked or they will be prohibited from being sold in the European Union (EU). Any product lacking the CE Mark after the deadline will be blocked from entry into the EU.

Implementing this directive essentially puts IVDs in line with other medical devices, since the In Vitro Diagnostics Directive is the final phase of the 3-phase Medical Device Directive (MDD). The first two phases of the MDD included: 1) the Active Implantable Medical Device Directive, which had an implementation deadline of January 1, 1995; and 2) the Medical Device Directive, which had its deadline on June 13, 1998.

The IVD Directive applies to reagents and reagent products, calibrator materials or instruments including specimen receptacles intended by the manufacturer for the in vitro examination of human tissue, blood or fluid samples for the purpose of providing information about a patient's state of health.

As stated earlier, compliance to the directive includes language translation of labeling, user instructions, or other key information into local languages as dictated by each EU Member State. Today, the European Union includes 15 Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Great Britain, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, and Sweden. It is also worth noting that in 2004, an additional ten countries will likely join the EU—with more added in 2007!

Companies are now faced with the dilemma of providing the appropriate and required information in a multilingual format while making the information readable on a variety of label sizes.

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The use of internationally recognized symbols as a substitute for text has been actively promoted to provide users with a uniform method of obtaining product information. Yet many diagnostics companies are struggling with the issues that surround multilingual label design and international symbols.

Some of the standards referenced by the Directive include EN 980 (medical device symbols), EN 375 (professional use labeling), EN 376 (self-testing labeling), EN 1658 (marking of IVD instruments) and ISO 15223 (medical device symbols). Exceptions among the EU Member States further complicate matters, since there are differences in how each Member State adopts the regulation. Some countries provide exemptions to local language requirements while others call for strict adherence to the Directive and may actually require that products be in several languages. Being informed about the national differences enables companies to determine if participation in a particular market is justified.

CE marking IVD products for Europe is a complex task. And there is confusion about how translation requirements are related to the CE Mark. Simply stated, the CE Mark is a European regulatory community sign and symbolizes the compliance of the product with the regulations relating to safety, public health, consumer protection, and the environment.

**Country Language Requirements**

| Country | Language(s) | Notes |
|---|---|---|
| Austria | German | National language requirement |
| Belgium | Dutch, French, German | Any one of the above as required by the professional user and all three for patient use. |
| Denmark | Danish | English was allowed for certain devices until 1998. |
| Finland | Finnish, Swedish | Information accompanying the device must be in Finnish, Swedish or English, unless the information takes the form of generally known directions or warning symbols. Information intended for users or patients to ensure the safe use of the device must be in Finnish and Swedish. |
| France | French | National language requirement |
| Germany | German | Other EU languages may be used for non-safety data. |
| Great Britain | English | English must be used on label. Insert may be in any EU language as long as it is stated on the label. |
| Greece | Greek | National language requirement |
| Ireland | English | National language requirement |
| Italy | Italian | National language requirement |
| Luxembourg | French, German, Luxembourgish, English | English accepted for professional use - patient information in French, German and Luxembourgish |
| Netherlands | Dutch | English can be used for professional use, but must be negotiated beforehand. |
| Portugal | Portuguese | National language requirement |
| Spain | Spanish | National language requirement |
| Sweden | Swedish | English can be used for professional use, but must be negotiated beforehand. |

IVD products must be CE marked by the December deadline or they can no longer be sold in the European Union.

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Some of the basic steps to achieve CE Marking are listed here.

- Verify if your product is an in-vitro diagnostic medical device and then categorize the device.
- Determine what materials need to be provided in local languages.
- Contact a Notified Body (The Notified Body will investigate the device through a series of questions to the manufacturer, confirm the categorization of the device, provide a cost and time estimate for CE marking, and choose the most suitable path to certification.)
- Apply for certification. (The Notified Body will then supply an assessment report, which may include testing requirements, operations audits, or other actions that the Notified Body deems appropriate for certification of your products.)

Remember, the IVDD was created to establish unified compliance standards throughout the EU to ensure the safety, quality and performance of in vitro diagnostic medical devices. Ultimately, this will make compliance easier and more efficient, since compliance will be harmonized across all EU Member States. However, it will take time and qualified resources to achieve successful compliance.

Welocalize can help by offering its integrated suite of globalization services with a focus on software applications, labels, and accompanying user documents for the Medical Device industry. We have dedicated translation teams and subject matter experts that bring experience and domain-specific expertise to your medical translation efforts. We stay current with the industry through membership in RAPS, Medical Alley, STC and by attending Medical Suds and TÜV events and trade shows.