EUROM VI "Medical Technology"

Mandatory Language Requirements for Medical Devices

Basis: National laws relating to the Medical Devices Directive 93/42/EEC

Country	for Label and Display	for Safety Instruction	for instruction for use
Austria	German	German	German, exception for professional use possible
Belgium	French, Dutch or German, depending on local area	ditto	ditto
Denmark	Danish	Danish	Danish
Finland	Finnish, Swedish or English for professional use; Finnish AND Swedish for public use	Finnish AND Swedish	Finnish, Swedish or English for professional use; Finnish AND Swedish for public use
France	French	French	French
Germany	German	German, except for justified cases in the language of the user	German, but for the user easily under-standable language possible
Greece	Greek	Greek	Greek
Iceland	Icelandic: For the professional user other languages (e.g. Swedish, Danish, Norwegian, German, English) are accepted	ditto	ditto
Ireland	English	English	English
Italy	Italian	Italian	Italian
Luxembourg	French or German, English for professional user accepted	ditto	ditto
The Netherlands	Dutch	Dutch	Dutch, but exemption for professional use, but permission from Comp.Authority
Norway	Norwegian for public use; for professional use other language may be used (English, Swedish, Danish)	ditto	ditto
Portugal	Portuguese	Portuguese	Portuguese
Spain	Spanish	Spanish	Spanish
Sweden	General: Information as mentioned in MDD annex 1 para 13 shall be in Swedish.	ditto	Swedish
Switzerland	French, German and Italian	French, German and Italian	French, German and Italian
United Kingdom	English	ditto	ditto

Country	for Label and Display	for Safety Instruction	for instruction for use
Estonia	Estonian, English and Finish for professional use	ditto	ditto
Latvia	Latvian	ditto	ditto
Lithuania	Lithuanian	ditto	ditto
Malta	English	ditto	ditto
Poland	Polish	Polish	Polish
Slovakia	Slovakian: For public use Slovene is mandatory; for the professional use English is accepted. For software used by professionals English is accepted.	ditto	ditto
Slovenia	Slovenian: For public use Slovene is mandatory; for the professional use English is accepted. For software used by professionals English is accepted.	ditto	ditto
Czech Republic	Czech	Czech	Czech

Country	for Label and Display	for Safety Instruction	for instruction for use
Hungary	Hungarian: Instructions for use for MDD and IVD products as well as reagent and other kit package inserts must be in Hungarian. For professional use only, MDD and IVD software is accepted in English or German according to the wish of the user. If software is not in Hungarian, the screen texts must be in Hungarian in the instructions for use. Software for the lay person must be in Hungarian. On labels international symbols can be used, as well as text in English (e.g. sterile) if the text is not an instruction or warning for safety	Hungarian: Instructions for use for MDD and IVD products as well as reagent and other kit package inserts must be in Hungarian. For professional use only, MDD and IVD software is accepted in English or German according to the wish of the user. If software is not in Hungarian, the screen texts must be in Hungarian in the instructions for use. Software for the lay person must be in Hungarian. On labels international symbols can be used	ditto
Cyprus	Greek for public use;, for professional use English is accepted. English also for software used by health professionals	ditto	ditto

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Depending on the Medical Devices Directive (93/42/EEC)- MDD - the member states of the European Economic Area, EEA, can require their own language. All of them have written the mandatory use of their own language for the information on the product and/or labelling depending on MDD annex I, paragraph 13 into their national law transposing the MDD.
The MDD says that the manufacturer has to deliver the information in one official language of the member states, which is up to him but he has to consider the contacts with the Competent Authorities and the Notified Bodies.

If a manufacturer delivers into other member states of the EEA he has to come to an agreement with the importer on the language:

- Either the manufacturer does the translation, then he has to prove the system for a correct translation to the Notified Body - if involved, or

- the importer organises the translation, then the manufacturer has to control that at least the safety instructions are correctly translated - for his own safety. The product liability remains in any case with the manufacturer, except the manufacturer can prove that the importer did the mistake.

Only the importer is bound by his national law, not the manufacturer in the other country. Therefore only the importer can decide if another language than his own could be used.

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