

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	dito	dito
Denmark	Danish	Danish	Danish
Finland	Finish, Swedish or English for professional use; Finish AND Swedish for public use	dito	Finish AND Swedish or English
France	French	French	French
Germany	German	German, except for justified cases in the language of the user	German, but for the user easily understandable language possible
Greece	Greek	Greek	Greek
Iceland	Icelandic: For the professional user other languages (e.g. Swedish, Danish, Norwegian, German, English) are accepted	dito	dito
Ireland	English	English	English
Italy	Italian	Italian	Italian
Luxembourg	French or German, English for professional user accepted	dito	dito
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)	dito	dito
Portugal	Portuguese	Portuguese	Portuguese
Spain	Spanish	Spanish	Spanish
Sweden	General: Information as mentioned in MDD annex 1 paragraph 13 shall be in	dito	Swedish

	Swedish.		
Switzerland	French, German and Italian	French, German and Italian	French, German and Italian
United Kingdom	English	dito	dito
Estonia	Estonian, English and Finish for professional use	dito	dito
Latvia	Latvian	dito	dito
Lithuania	Lithuanian	dito	dito
Malta	English	dito	dito
Poland	Polish	Polish	Polish
Slovakia	Slovakian: For public use Slovakian is mandatory; for the professional use English accepted. For software used by professionals English accepted	dito	dito
Slovenia	Slovenian: For public use Slovene is mandatory; for the professional use English accepted. For software used by professionals English accepted	dito	dito
Czech Republic	Czech	Czech	Czech
Hungary	Hungarian: Instruction 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 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: Instruction 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 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	dito
Cyprus	Greek for public use; for professional use English is accepted. English also for software used by health professionals	dito	dito