Mandatory Languages Requirements for Medical Devices

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

In red the MS not yet checked.

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 exemptions possible for professional use under certain conditions	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, in justified cases another language easily understood by the user or other means can be used	German or the language of the user	German, in justified cases another language easily understood by the user or other means can be used
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
Liechtenstein	German	German	German
Luxembourg	French or German, English for professional users accepted	ditto	ditto
The Netherlands (exemption for maximum 5 years)	Dutch	Dutch	Dutch, but exception for professional use, but permission from Competent Authority
Norway	Norwegian	ditto	ditto
Portugal	Portuguese	Portuguese	Portuguese
Spain	Spanish	Spanish	Spanish
Sweden	Swedish	Swedish	Swedish
Switzerland	French, German and Italian	French, German and Italian	French, German and Italian
United Kingdom	English	ditto	Ditto
Estonia	For Label: Estonian, for professional users it can be in English For Display: it can be in English or in some other languages if it is	Minimum information shall be in Estonian	For lay user in Estonian and for professional user it can be in English

	understandable for potential user.		ditto
Latvia	Latvian	ditto	ditto
Lithuania	Lithuanian	Lithuanian	Lithuanian
Malta	Maltese and/or English	Maltese and/or English	Maltese and/or English
Poland	Polish For the professional user other languages are accepted after user acceptance	Polish For the professional user other languages are accepted after user acceptance	Polish For the professional user other languages are accepted after user acceptance
Slovakia	Slovakian	ditto	ditto
Slovenia	Slovenian	Slovenian	Slovenian
Czech Republic	Czech	Czech	Instructions for use must be in Czech language for public use; for the professional use information required for the safe use of the product has to be in the czech language, all other parts of the User Manuals can be in English (for the all MD). User Interface can be in English, provided that the information required for the safe use of the product is included in czech language into User Manual (or into another document available for the user).
Hungary	Hungarian: Instructions for use for MDD and IVD products as well as reagent and other kit package inserts must be	Hungarian: Instructions for use for MDD and IVD products as well as reagent and other kit package inserts must be	ditto

	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	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	
Cyprus	Greek for public use;, for professional use English is accepted. English also for software used by health professionals	ditto	ditto
Bulgaria	Bulgarian, for professional users it can be in English or in any other language if it is understandable for potential user.	Bulgarian	Bulgarian
Romania	Romanian	Romanian	Romanian