Mandatory Languages Requirements for Medical Devices

Basis: National laws relating to the Medical Devices Directive 93/42/EEC (оригинал [тут](https://www.team-nb.org/wp-content/uploads/2015/05/documents2012andolders/MDEG_-_2008-12_-_II-6.3._Mandatory_Languages_Requirements_for_Medical_Devices_update_Sept.08.pdf))

**In red the MS not yet checked**

| **Country** | **for Label and Display** | **for Safety Instruction** | **for instruction for use (IFU)** |
| --- | --- | --- | --- |
| Austria | German | German | German, exception for professional use possible |
| Belgium | French, Dutch or Germanexemptions 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 use | 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 understandable for potential user. | Minimum information shall be in Estonian | For lay user in Estonian and for professional user it can be in English |
| 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 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  |
| 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 |