**Language requirements for information about medical devices**

**Austria**

8.3. Labelling and instructions for use: According to the Austrian Act on Medical Devices MPG § 9 Abs. 6 information on packages and in the patient leaflet etc. has to be in German , regardless of whether the target persons are lay or professional users. The manufacturer and/or the authorised representative have to be named on the package.

<http://www.medizinprodukteregister.at/de/english-version7>

**Bulgaria**

MEDICAL DEVICES ACTArt. 16

(1) Manufacturers of medical devices shall be obliged to specify their name,

headquarters and business address on the device, its packing and instructions for use. Instruction for use

is not required for devices under Art.2, para.1, item 3 from class I and IIa which, in the manufacturer’s

opinion can be used safely without instructions for use.

(2) The name and address of the authorized representative and of the importer are additionally

specified on the packing and in the instructions for use of devices which are imported from third

countries on the territory of the European Union or on the territory of the European Economic Area.

(3) **The instruction for use shall also be written in Bulgarian language**.

**<http://www.bda.bg/images/stories/documents/legal_acts/ZMI_en_20160308.pdf>**

**Croatia**

Medical Devices Act (Official Gazette No. 76/13) - Art 12

(5) **The instructions for use and labelling of the medical device must be in the Croatian**

language and appear in a visible and legible and form.

(6) Where the instructions for use and labelling referred to in paragraph 5 of this Article are

translated the Croatian language, the translation of the instruction for use and marking of the

medical device must equally correspond to the original instructions for use and marking of the

medical device.

(7) The instructions for use of medical devices **exclusively intended for use by medical institutions must be supplied in a language which is known by the user**.

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**Denmark**

**Labelling and instructions for use for medical devices must be in Danish.**

Any information, printed and electronic, which is necessary for the safe and correct use according to the purpose of the device (as described by the manufacturer), must be in Danish when the devices is made available to the final user.

**Software and service manuals**

The executive orders do not require that software and service manuals must be provided in Danish. **The manufacturer is responsible for defining which information is necessary for the correct and safe use of the device.**

**Display, buttons and keys**

Single words or phrases, such as "Load", "Enter", "Page Down" or the like, are considered to be symbols. Symbols are not required to be translated, but must be explained in the instructions for use.

If the information involves more than two words and provides information/instructions to the user, this must be in Danish, **see the above-mentioned exemption**.

<https://laegemiddelstyrelsen.dk/en/devices/registration-and-marketing/language-requirement/>

**Estonia**

Medical devices act

§ 16. Requirements for placing on market and putting into service of medical devices

(3) T**he information strictly necessary for the safe use of a medical device for its intended purpose accompanying a medical device to be placed on the market, distributed and put into service in Estonia shall be presented in the Estonian language** and in an appropriate manner, taking account of the knowledge of the potential user of the device. The remaining information accompanying a device may be presented in another language of a Member State of the European Economic Area understandable to the potential user. The person who places the medical device on the market in Estonia or the distributor shall ensure the correctness of translation of the instructions of a medical

**Greece**

Mail answer 11 July 2018

For the Distribution of all CE marked medical devices in Greece it is mandatory that the labelling and instructions for use are complete and accurate in the Greek language.

There is an exception for devices distributed only for professional use, but in this case you should have permission by the National Organization For Medicines in Greece (EOF), Marketing Surveillance Section and labels and IFU must be made available in English. Contact e-mail: market-surveillance@eof.gr mailto:market-surveillance@eof.gr

Maria Katsimpoula
Assessor
Medical Devices Assessment Section
National Organization for Medicines (EOF)

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The CE mark on medical devices is recognised by all EU member states. There are no further requirements for the commercialisation of medical devices imported from other EU member states (except that **usage information must be in the Greek language**).

[https://uk.practicallaw.thomsonreuters.com/w-013-1410?transitionType=Default&contextData=(sc.Default)&firstPage=true&comp=pluk&bhcp=1#co\_anchor\_a479050](https://uk.practicallaw.thomsonreuters.com/w-013-1410?transitionType=Default&contextData=(sc.Default)&firstPage=true&comp=pluk&bhcp=1" \l "co_anchor_a479050)

**Hungary**

Mail answer 10 July 2018

In spite of the content of certain information widely available on the Internet, we would like to make it clear that both **the label and the instructions for use of the medical device, as well as the information on the display must be in Hungarian, regardless of whether the device is for professional or other use**.

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NATIONAL IMPLEMENTING LEGISLATION (of art 4(4) of the MDD)

Article 13.7 of 4/2009 (III. 17.) Decree of the Hungarian Minister of Health provides that "the information given by the manufacturer to the user and to the patient, in accordance to Annex I 13.1-13.6 points of the Directive, must be in Hungarian.” (Same for IVD devices in IVD decree).

The above mentioned language requirements are uniform and not dependent on a specific group of users (professional or non-professional) intended by the manufacturer.

The information that appears on the display acceptable as a symbol, a pictogram, graphic illustration etc. or a short text in foreign language provided that the meaning of them are unambiguously explained by clear illustrative drawings and related Hungarian explanatory text in the instructions for use.

If the texts that are displayed on screen are typically longer texts, manufacturer should take action to issue Hungarian language patch for the softwer.

**Kornel Szerdi J.D.**

Acting Head of Department

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**Iceland**

MDEG-2008-12 – II-6.3

For the professional user other languages (e.g. Swedish, Danish, Norwegian, German, English) are accepted

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All medical devices should include information on manufacturer and required guidelines on safe an effective use, which should take into account the level of education and knowledge of potential users. These guidelines should be located either on the device itself or on it its packaging. The languages of the guideline should be clearly specified and in these cases where patients themselves operate the medical device the guidelines should be in Icelandic.

<https://www.ima.is/medical_devices/about_medical_devices/>

**Latvia**

Mail answer 10 July 2018

According to the Regulations of the Cabinet of Ministers No.689, adopted November 28, 2017 “Procedures for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices” (hereinafter – Regulation No. 689), information, which is available to the user and the patient so that the medical device can be used in accordance with the intended purpose, shall be in the official language.

The Official Language Law lies down that for any imported devices, t**he labelling, instructions for use,** guarantee documents or technical certificate which includes information in a foreign language, **shall have attached thereto a translation of such information in Latvian language. If a foreign language is used concurrently with Latvian language, the text in Latvian language shall be placed in primary position, and it may not, in its form or contents, be smaller or narrower than the text in the foreign language.**

Sincerely yours **Inga Delikatnaja**
Medical Devices Evaluation Department
Senior Expert

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| --- | --- |
|  | **State Agency of Medicines of the Republic of Latvia**Jersikas street 15, Riga, LV-1003, LatviaPhone: +371 67078466, Fax: +371 67078428[www.zva.gov.lv](http://www.zva.gov.lv/)  |

**Lithuania**

At the point when the device reaches the final user, irrespective of the users competence (professional or not), **all information supplied by the manufacturer (label, instructions for use) must be in Lithuanian language**.

<http://www.vaspvt.gov.lt/en/node/275>

**Romania**

MDEG-2008-12 – II-6.3

Romanian

**Slovakia**

MDEG-2008-12 – II-6.3

Slovakian

**Slovenia**

<http://www.adde.info/frontend/files/userfiles/files/mandatory_requirements_for_medical_devices.pdf>

Slovenian: For public use Slovene is mandatory; for the professional use English accepted. For software used by professionals English accepted

**Sweden**

Something which manufacturers in particular have to observe, is that **labelling and instructions for use** (users manual, **display, voice** etc.) according to paragraph 4 in the Regulations (LVFS 2001:5, LVFS 2003:11 and LVFS 2001:7 respectively) s**hall be written in Swedish**. This is irrespective of the device being used by a patient or by trained staff or if the device is used in a hospital or in an accommodation. Service manuals might be in English.

<https://lakemedelsverket.se/english/product/Medical-devices/An-Introduction-to-Rules-and-Regulations/>

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**Netherlands**

In the Netherlands, l**abels and instructions for use must be in Dutch.** This requirement is contained in Article 6 (2) of the Medical Devices Decree (Dutch) and article 6 of the In-vitro Diagnostic Medical Devices Decree (Dutch). It covers devices used widely, not those only used by health care professionals.

Medical devices and IVD's supplied only to professional users (such as doctors, nurses and laboratory professionals) may be accompanied by instructions for use in English only. The manufacturer must make sure that the product will be used only by professional users with a sufficient command of English. The manufacturer is required to keep a watch on this matter by means of the legally required post-market surveillance system. A manufacturer that discovers that the product is being used by non-professional users or by professional users without a sufficient command of English must provide the information in Dutch.

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