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Language implications of MDR for labelling of Medical Devices (MD)

October 2020 (Version 2 replacing version of January 2020)

Introduction

This guidance document has been developed by the MedTech Europe Labelling working group (MD). Use of this guidance is voluntary, and reliance on it should only be undertaken after an independent review of its accuracy, completeness, efficacy and timeliness.
The translations provided below are unofficial for reference only. The original text of the national laws should be consulted in case of doubt.
In the preparation of this Guidance, MedTech Europe has used its best efforts to ensure that the opinions, translations and advice expressed are sound. However, the Association makes no assertion that those are correct, and it accepts no legal responsibility for them. Specific legal advice should be sought before acting on any of the topics covered.

The MDR makes provisions in several places that the documentation submitted with the device shall be made available in the language(s) accepted in the Member State where the device is being sold.
Therefore, this document is intended to give a summary of the language requirements put in place by the European countries for medical devices' Instructions for Use (IFU) and label under the regulatory regime of the Medical Devices Regulation (MDR) 2017/745/EU.

The list includes all EU Member States, EEA, EFTA members and Turkey. The information for this list was obtained from MedTech Europe National Associations and Corporate Members. References to specific national laws were made where the information was available. Please note not all EU Member States have yet updated their legal framework for the MDR. In some countries, national provisions are in draft stage and in others the language requirements of the Directives are still indicated as valid since no update has been undertaken. The information for software labelling has been included where it was available. MedTech Europe reserves the right to change or amend this document at any time without notice in order to keep the information up to date. It is foreseen to update this overview once further national provisions are put in place.

***NEW:** The current version of October 2020 does not include significant changes from the previous version. References to laws were added where missing or updated. The key changes to bring to the members' attention are marked with ***NEW** or ***UPDATED.**

Under MDR there is other documentation that will require translations into local languages, such as SSCP. As per the MDCG guidance on SSCP (MDCG 2019-9) the translations of SSCP (Summary of Safety and Clinical Performance) are to be done in an analogous way with the IFU requirements in the given Member State. The SSCP part for patients must be always in the local language.

Note: Eudamed set up **does not** provide for 2 separate SSCP documents (one for patients and one for professionals). The SSCP will be one document. For more details, please consult the aforementioned MDCG guidance.

Based on the currently available information, regarding the Declaration of Conformity (DoC) only Czech Republic requires it in the Czech language. This information is based on a draft law and is included in the table below.

Detected key language requirement changes

*Iceland – Icelandic required for patient use IFU and patient use software

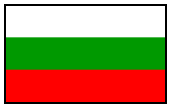
*Poland – English now allowed for label and IFU for professional use. (draft law)

*Belgium – English allowed for label and IFU for professional use (draft law)

Summary table with legal references and notes

Austria	Language Requirements	Notes
	**German**	§9 MPG (Medizinproduktegesetz) clause 6 : https://www.jusline.at/gesetz/mpg/paragraf/9 Version of the MDD/AIMDD. Medical devices may only be supplied to the user or consumer if the information intended for him or the patient is written in **German**. There may be some exceptions under specific circumstances. German will be required equally under the MDR regime.

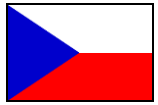
Belgium	Language Requirements	Notes
	**French and Dutch and German** **For professional use English is acceptable**	Belgium has not yet officially published languages requirements for MDR (as of November 2019). The Proposed Belgium law of 08102019, says the following : For lay users: all information given by the manufacturer (IFU, labels, packaging (and if possible and appropriate information on the device itself and the packaging of each unit) must be at least in the 3 national languages (Dutch, French and German) For professional users: it might be in English. In this case, however, the user may require the manufacturer to provide this information in the national language of his choice. The manufacturer may respond to this request electronically.

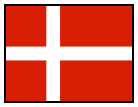
Bulgaria	Language Requirements	Notes
	**Bulgarian**	According to the regulations in force, Medical device Act/2007, art. 16 (3) *The instruction for use shall also be written in Bulgarian language*.

Croatia	Language Requirements	Notes
	**Croatian (and English)** ***UPDATED**	Agency for Medicinal products and Medical Devices of Croatia confirmation of language requirements for professional use labelling: In regards to article 30(2) of the Implementation act of Regulation (EU)2017/745 on Medical Devices and Regulation (EU)2017/746 on In vitro Diagnostic devices (NN 100/18) is related to the information which a Manufacturer must provide with the device (Section III of ANNEX I of the Regulation (EU)2017/745) – labelling and Instructions for use. Medical Devices destined for non-specialized users, (patients) is mandatory, that the IFU and labelling be provided in Croatian. On the other hand, for Medical Devices, which are to be used exclusively in the context of medical practice, the IFU may be in Croatian and/or in English, which means that professional users who can understand English may use devices whose IFU/labelling is in English.

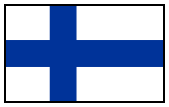
Cyprus	Language Requirements	Notes

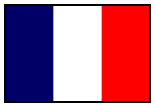
Greek (and English) 	Law 30 (I)/2002 relating to the Basic Requirements of Certain Categories of Products Basic Requirements (Medical Devices) Regulations 598/ 2003. **Please note this is based on the MDD.** Product label: Greek or English accepted for professional use Packaging label: English accepted for professional use IFU: Greek or English accepted for professional use Software: Greek or English accepted for professional use

Czech Republic	**Language Requirements**	**Notes**
	**Czech** ***UPDATED**	*New draft law (first reading in the Parliament soon):* *i) The manufacturer shall be required to provide any information to user, accompanying a device, in Czech. This information is further categorized in Section 23 of Annex I into: instructions for use and label on the packaging. Both types of information shall be provided in Czech. Czech language shall be required also for cards related to implants (Article 18). However, the label may be language-neutral if ISO symbols are used.* *ii) The language requirements do not contain any exceptions for devices "for professional use". It is even health care provider obligation to avoid use of medical device if instructions for use is not available in Czech.* **Regarding DoC please note:** **Art.8 (1), Draft act on medical devices, available in CZ only.** ***''Manufacturer has the obligation to ensure translation of the Declaration of conformity into Czech language, if the device is to be sold on the Czech market''***

Denmark	**Language Requirements**	**Notes**
	**Danish**	Acts Act No. 139 of 15 February 2016 concerning medical devices Act No. 3 of 3 January 2019 – The Danish Product Safety Act 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. https://laegemiddelstyrelsen.dk/en/devices/registration-and-marketing/language-requirement/

Estonia	Language Requirements	Notes
	**Estonian**	https://www.terviseamet.ee/en/labelling-and-language-requirements-medicaldevices The information on the sales packaging (including the product name, if applicable) has to be in the Estonian language. The minimum packaging information is required to ensure the safe and appropriate use of the medical device must be in Estonian and must be displayed in an appropriate manner, taking into account the knowledge of the potential user. **Other information** concerning the medical device may be in any other European Member State language **(English is most preferable),** provided it is understandable by the user. The same principles apply to products meant only for the Estonian internal market.

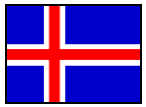
Finland	Language Requirements	Notes
	**Finnish and Swedish (**or English**)**	Summary of language requirements for labeling and IFUs in Finland as of October 2019: based on Medical Devices Act, 12 § (629/2010, amended in 2017). National legislation to be revised early 2020. Change of language requirements not foreseen for the moment. In general, labeling and IFUs can be given in Finnish, Swedish or English. Information intended for users or patients to ensure the safe use of the device must be in Finnish and Swedish. Also, the instructions for use and labelling of medical devices intended for self-testing must be in Finnish and Swedish.

France	Language Requirements	Notes
	**French**	Code de la Sante publique - Article R5211-20 *L'étiquetage d'un dispositif médical remis à l'utilisateur final ou le patient, la notice qui l'accompagne, ainsi que toute autre information relative à son fonctionnement ou à son utilisation comportent une version rédigée en français.* Label and all accompanying information must be in French. These requirements will apply for devices under MDR. Version in force since 2004.

Germany	Language Requirements	Notes
	**German,** in justified cases English acceptable ***UPDATED**	**New German law: Gesetz zur Anpassung des Medizinprodukterechts an die Verordnung (EU) 2017/745 und die Verordnung (EU) 2017/746 (Medizinprodukte-EU-Anpassungsgesetz – MPEUAnpG)***

	§ 8 Language regime for the EU Declaration of Conformity and for product information (1) The manufacturer shall, for products within the scope of this law on the market the EU Declaration of Conformity according to Article 19 Paragraph 1 of Regulation (EU) 2017/745 in German or in English language. (2) Within the scope of this Act, products may only then given to users and patients if the information available to users and patients certain information in German language for can be made available. In justified cases the information also in English language or another for the user of the medical device made available in easily understandable language if this information is used exclusively for are intended for professional users and the safety related Information also in German language or in the language of the user can be set. (3) The manufacturer of an implantable product has received the information referred to in Article 18(1), subparagraph 1 of the regulation (EU) 2017/745 in German language to be made available

Greece	**Language Requirements**	**Notes**
	**Greek**	Directive 93/42/ΕΕ, national legislation decree ΔΥ8δ/Γ.Π.οικ130648/ΦΕΚ 2198Β/02-10-2009 article 4 par 4 and Directive 2017/745 chapter II article 10: Article 4 Free movement of designated products 4. The **information to be made available to the user and patient** in accordance with Annex I, point 13, must be complete and accurate in the **Greek language when delivered to the end user, whether for professional or other use**. Any contraindications or side effects should be explicitly reported.
Hungary	**Language Requirements**	**Notes**
	**Hungarian**	Language requirements of the label and Instruction for use : If the product is available on the Hungarian market, the IFU and label of medical devices must be available in Hungarian https://www.ogyei.gov.hu/medical_devices

Iceland	Language Requirements	Notes
	**English** **! Icelandic !**	English for professional use IFU and software for professional use. **NEW:** Icelandic for patient use IFU and software for patient use.

Ireland	Language Requirements	Notes
	**English** (or English and Irish)	S.I. No. 547 of 2017. EUROPEAN UNION (MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES) REGULATIONS 2017 Language provisions – point 5.

Italy	Language Requirements	Notes
	**Italian**	Italian Decree, *Ref. art.5 par.4.* (as transposed for the MDD), states that labels, instructions for use, and any other information for the user shall be in Italian language and this is the responsibility of the manufacturer. The Italian MoH is expected to issue a specific national provision stating the same for the MDR, (e.i. that the labelling is required to be provided in the Italian language).

Latvia	Language Requirements	Notes
	**Latvian**	According to the Regulation No. 689 of the Cabinet of Ministers of the Republic of Latvia "Procedure for Registration, Assessment, Distribution, Exploitation and Technical Supervision of Medical Devices" adopted on 28 November 2017, 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**. https://www.zva.gov.lv/en/industry/medical-device-manufacturers-authorized-representatives/being-placed-market

Liechtenstein	Language Requirements	Notes
	**German**	https://www.llv.li/inhalt/1313/amtsstellen/marktzugang-und-pflichten The language for IFU and label is German. Exceptions are possible if the medical device is sold exclusively to specialists, if it is a

	custom-made product or an in-house manufactured medical device. It must be ensured that the user has the necessary technical and linguistic qualifications and agrees with the language restrictions.

Lithuania	Language Requirements	Notes
	**Lithuanian**	Published from the State Health Care Accreditation Agency under the Ministry of Health: *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

Luxembourg	Language Requirements	Notes
	**French or German or Luxembourgish**	4. Les indications qui doivent être fournies à l'utilisateur et au patient conformément à l'annexe I point 13 doivent être rédigées dans une des langues française, allemande ou luxembourgeoise lors de la remise à l'utilisateur final, que ce soit pour utilisation professionnelle ou autre. **Règlement grand-ducal du 11 août 1996 relatif aux dispositifs médicaux** http://data.legilux.public.lu/file/eli-etat-leg-memorial-1996-61-fr-pdf.pdf

Malta	Language Requirements	Notes
	**English or Maltese**	For MDs and IVDs is accepted in Maltese and/or English as stipulated by Article 6.4 in our LN. The intention is the language for labelling and IFUs will most probably remain the same under the new MDR.

The Netherlands	Language Requirements	Notes
	**Dutch. English for professional use (IFU and label)**	https://www.eerstekamer.nl/wetsvoorstel/35043_wet_medische_hulpmiddelen - MDR law published on November 11, 2019 User has the right to request the information in Dutch.

Norway	Language Requirements	Notes
	**Norwegian**	https://lovdata.no/dokument/SF/forskrift/2005-12-15-1690/KAPITTEL_2-3#%C3%82%C2%A72-6 § 2-6 (language) Information as mentioned in AIMU I nos. 13, 14, and 15, IVDMU I part B no. 8, or EMU I no. 13 shall be in Norwegian. The information may be provided with harmonized symbols, recognized codes or other equivalent solutions, provided that safe and correct use is ensured. For equipment for clinical trials, languages other than Norwegian can be used if this is accepted by the user, but information intended for the patient must still be in Norwegian. If safe and correct use is ensured, the supervisory authority may make an exception to the requirement for a Norwegian language.

Poland	Language Requirements	Notes
	**Polish** ***UPDATED**	Information/user interface for patients must be in Polish. Medical devices intended for professional users in Poland may have IFU and labeling in English. **English is accepted when it is a product delivered to providers who have given a written consent to receive labels and IFUs in English:** **This information is based on a draft law that will enter into force in the near future and not on currently binding regulations.** **Draft Polish Law – version of 3 July** on medical devices "implementing" MDR: *Art. 14.* *1. Wyroby przeznaczone do używania na terytorium Rzeczypospolitej Polskiej mają oznakowania i instrukcje używania w języku polskim lub wyrażone za pomocą zharmonizowanych symboli lub rozpoznawalnych kodów.* *2. Dopuszcza się, aby wyroby przeznaczone do używania na terytorium Rzeczypospolitej Polskiej dostarczane świadczeniodawcom, za ich pisemną zgodą, miały oznakowania lub instrukcje używania w języku angielskim, z wyjątkiem informacji przeznaczonych dla pacjenta, które podaje się w języku polskim lub wyraża za pomocą zharmonizowanych*

	symboli lub rozpoznawalnych kodów. *3. Jeżeli oznakowanie wyrobu jest w języku polskim, to również instrukcja używania wyrobu jest w języku polskim lub w postaci zharmonizowanych symboli lub rozpoznawalnych kodów.* *4. Jeżeli oznakowanie opakowania zbiorczego jest w języku polskim, to oznakowanie opakowania jednostkowego jest również w języku polskim lub w postaci zharmonizowanych symboli lub rozpoznawalnych kodów.* *5. Wyroby są transportowane, składowane oraz przechowywane w warunkach zapewniających ich nienaruszalność, zachowanie właściwości oraz bezpieczeństwo pacjentów, użytkowników i osób trzecich* *Art 14.* *1.Medical devices intended for use on the territory of the Republic of Poland have labels and instructions for use in Polish or expressed by means of harmonized symbols or recognizable codes.* *2.It is allowed that medical devices intended for use on the territory of the Republic of Poland and delivered to providers with their written consent, have labels and instruction for use in English, with the exception of information intended for the patient, which is given in Polish or expressed by means of harmonized symbols or recognizable codes.* *3. If the label of a medical device is in Polish, the instructions for use shall be in Polish or in the form of harmonized symbols or recognizable codes.* *4. If multiple devices packaging label is in Polish, then the packaging label of each unit shall be in Polish or in the form of harmonized symbols or recognizable codes.* *5. A medical device intended for use on the territory of the Republic of Poland has a user interface in Polish or in the form of harmonized symbols or recognizable codes.* *6. Medical devices are transported, stored and kept in conditions ensuring their integrity, preservation of properties and the safety of patients, users and third parties.*

Portugal	**Language Requirements**	**Notes**
	**Portuguese**	Decreto-Lei n.º 145/2009 de 17 de Junho, CAPÍTULO II (CHAPTER II) Requisitos para a colocação no mercado e presunção da conformidade (Requirements for placing on the market and compliance presumption), Artigo 5 (Article 5): The **labelling and instructions for the use of any devices should be drawn up in the Portuguese language** regardless of whether they are intended for professional or lay use. Please note information is from 2009 and therefore still based on MDD.

Romania	Language Requirements	Notes
	**Romanian**	**Decision no. 54/2009** brings more specific details**:** **Chapter II** - Conditions for placing on the market and putting into service of medical devices **Section 3** - Free movement of medical devices **Art. 11. 4)** When a device reaches the final user, whether or not the device is for professional use, the information provided for in point 13 of Annex 1, made available to the user and the patient, must be written in Romanian **Decision no. 55/2009 Annex 1** brings more specific details**:** **Chapter II:** Placing on the market of active implantable medical devices Art.10.4) When a device is put into operation, the information provided in point II, items 8,9, and 10 of the annex no 1 must be written in Romanian. **Government decision no.798/2003** brings more specific details: **Section 3** – Free circulation **Art. 10. 4)** The follow-up of the care may be provided according to the annex no.1 part B point 8 will be written in Romanian when the end user can be reached. **7)** For self-testing devices, instructions for use and labeling must be accompanied by a translation into Romanian. **Law no 296/2004** regarding the Consumer Code **Art 50** The information on the labels of the products must be written in the Romanian language,regardless of the producing country, without excluding their presentation and in other languages, to be visible, readable and inscribed in a way that does not allow the deletion thei.

Slovakia	Language Requirements	Notes
	**Slovak**	Labelling of medical device products have to be in local language and the data source available in www.sukl.sk.

Slovenia	Language Requirements	Notes
	**Slovene**	Source: Pravilnik o medicinskih pripomockih Regulation on Medical Devices (Ur.l.82/00), article 4.4 Article 33of Medical Devices Act of the Republic of Slovenia (ZMedPri):

	(5) The instructions for use must be written in the Slovene language, legible and understandable for the user, and must contain the date of issue or the date of last revision or amendment. If they have been translated into the Slovene language, the content of the translation must be the same as that of the original package leaflet. **If a medical device is intended solely to be used for performing a registered activity (e.g.professional use), the instructions for use can be written in the language understandable for the user.** **-> this could be English or other language understandable to the user.** (Need for a statement signed by the user indicating that he is able to understand the IFU and label in that language.) English allowed for software for professional use, if steps/screens are explained in IFU.

Spain	Language Requirements	Notes
	**Spanish**	**17606** - *Real Decreto 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios* Art. 4 , Section 2; *When the products are put into service within Spain, the products must include the data and information contained in section 13 of annex I, at least in Spanish, so that effective, accurate and adequate information on their essential characteristics is available in a clear and objective way*. Label and IFU must be in Spanish. These requirements will apply to devices under MDR

Sweden	Language Requirements	Notes
	**Swedish**	Swedish law on the languages for medical devices: Law 1993:584 updated 2005

Switzerland	Language Requirements	Notes
	**German and French and Italian** **English for professional use** ***UPDATED**	Labelling information must be in the three official languages but for professional use English is allowed Source : Medizinprodukteverordnung(MepV), 1 July 2020 https://www.bag.admin.ch/bag/it/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte/revision-med-prod-verord-mepv.html https://www.admin.ch/opc/it/official-compilation/2020/2977.pdf

Turkey	Language Requirements	Notes
	**Turkish**	''the information, user manuals, labels, maintenance-repair booklet and other statements required to be provided to patients, users and practitioners with the medical device by the producer must be in **Turkish** when the medical device is supplied to the market'' Source: Ürün Takip Sistemi (ÜTS), Tıbbi Cihazların Etiketleri Hakkında, D U Y U R U

United Kingdom	Language Requirements	Notes
	**English**	

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

The Medical Devices Regulation contains several provisions that are capable of being given more than one interpretation. In the preparation of this Guidance, MedTech Europe has used its best efforts to ensure that the opinions and advice expressed are sound. However, the Association makes no assertion that those opinions and advice are correct and it accepts no legal responsibility for them. Specific legal advice should be sought before acting on any of the topics covered. MedTech Europe reserves the right to change or amend this document at any time without notice in order to keep the information up to date.

Members are reminded that, while competent authorities and notified bodies may be helpful in providing views as to the meaning of the MD Regulation, it is ultimately for the courts to interpret legislation.

For more information, visit www.medtecheurope.org.

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