EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
**Medical Devices**

**MDR - language requirements for manufacturers** (January 2024)

Regulation (EU) 2017/745 on medical devices (MDR) contains different legal provisions that allow Member States to determine language requirements for manufacturers at national level for information accompanying the device. The following table gives an overview of the national provisions, in the case that Member States have made use of the possibility to determine language requirements for manufacturers. Member States are not obliged to determine a specific language. Having regard to the costs related to providing information in various languages, Member States are encouraged to consider whether information to be provided by the manufacturer could be accepted in another language than their national language (e.g. in English) if the safe use of the device is not compromised, especially regarding devices for professional use.

*The below information is provided based on the information available to the Commission services following a consultation of the Medical Device Coordination Group (MDCG) in October 2023. The Commission services do not take responsibility for the correctness of the information in the table. In any case, the provisions of the MDR and the provisions of the Member States implementing the MDR in respect of language requirements take precedence over the information in this table.*

| **Country** | **Relevant legal provision (reference and hyperlink to official publication)** | **Label/IFU (Art. 10 (11), Annex I, section 23, MDR)** | | **Implant card (Art. 18 (I) MDR)** | **Declaration of conformity (Art 19 (I) MDR)** | **Field safety notice (Art. 89 (8) MDR)** | **Documents for conformity assessment (Art. 52 (12)** | **(Graphic) user interface (e.g. Apps)** | |
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| | | **Patient/lay user** | **Professional user** | | | | | **Patient /lay user** | **Professional user** |
| **Austria*** | Bundesgesetz betreffend Medizinprodukte<br>30 June 2021<br><br>Medizinproduktegesetz-2021 | German<br>(§7 para 1)* | German or English<br>(§7 para 1)* | German<br>(§7 para 4)* | German<br>(§7 para 2)* | German<br>(§7 para 6)* | German or English<br>(§7 para 7 No. 1)* | | |

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| **Belgium** | Wet betreffende medische hulpmiddelen 18 January 2021<br><br>2020_12_22_Law_on_Medical_Devices.pdf (vbb.com) | French, Dutch and German (Art. 9 para 1) | French, Dutch, German or English (Art. 9 para 1) | French, Dutch, German or English (choice of the patient) (Art. 13 para 3) | French, Dutch, German or English (Art. 14) | French, Dutch and German; in case user is a healthcare professional English is allowed (Art. 65) | French, Dutch, German or English (Art. 24) | Considered as the Label/IFU information: French, Dutch and German (Art. 9 para 1) | Considered as the Label/IFU information: French, Dutch and German or English (Art. 9 para 1) |
| **Bulgaria*** | LAW ON MEDICAL DEVICES (bda.bg)<br>12 June 2007<br><br>Medical devices - Bulgarian Drug Agency (bda.bg) | Bulgarian (Art. 28 para 2 No. 4)* | Bulgarian (Art. 28 para 2 No. 4)* | | | | | | |
| **Croatia** | Act implementing Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices<br>22 November 2018<br><br>Zakon.hr | Croatian (Art. 30) | Croatian and/or English (declaration/agreement of professional user needed) (Art. 30). “or” is to be read as without prejudice to Art. 10(p.11) MDR – information supplied should be clearly comprehensible to the intended user | Croatian (Art. 30) as the card is intended for patients | Croatian and/or English (Art. 30) | Croatian and/or English (Art. 30) | Croatian and/or English (Art. 30) | Any GUI elements linked to performance or safety should follow the same rules as label/IFU. | Any GUI elements linked to performance or safety should follow the same rules as label/IFU. |
| **Cyprus** | Cyprus Medical Devices Authority<br>Regulatory Information<br>Ιατρικές Υπηρεσίες (moh.gov.cy) | Greek | Greek or English | Greek or English | Greek or English | Greek or English | Greek or English | Greek | Greek or English |

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| | Law 30 (I)/2002 relating to the Basic Requirements of Certain Categories of Products Basic Requirements (Medical Devices) Regulations 598/2003. | | | | | | | | |
| **Czech Republic** | https://www.zakonyprolidi.cz/cs/2021-89/zneni-20210526<br>1 March 2021<br><br>375/2022 Sb. Zákon o zdravotnických prostředcích a diagnostických zdravotnických prostředcích in vitro (zakonyprolidi.cz)<br>7 December 2022<br><br>https://www.niszp.cz/sites/default/files/dokumenty/ZoZPaIVD_AJ%20verze.pdf | Czech<br>(§8 para 2) | Czech<br>(§8 para 2) | Czech<br>(§8 para 2) | Czech, Slovak or English (§8 para 1) | Czech<br>(§ 8 para 2) | Czech, Slovak or English<br>(§ 8 para 1) | Czech | Czech or English |
| **Denmark** | Executive Order no. 837 of 20 June 2023 on Medical Devices etc.<br>Bekendtgørelse om medicinsk udstyr m.v. (retsinformation.dk)<br>Language requirement for information about medical devices (laegemiddelstyrelsen.dk) | Danish<br>(Chapter II § 3) | Danish; English possible upon request<br>(Chapter II § 3 para 2) | Danish, exception English<br>(Chapter II § 4 para 2 ) | English,<br>Danish in specific cases<br>(Chapter II § 6) | | | https://www.retsinformation.dk/eli/retsinfo/2021/9840<br><br>Danish Guidance, section 2<br><br>Language requirement for informatio | https://www.retsinformation.dk/eli/retsinfo/2021/9840<br><br>Danish Guidance, section 2<br><br>Language requirement for informatio |

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| | | | | | | | | n about medical devices(lægemiddelstyrelsen.dk) | n about medical devices(lægemiddelstyrelsen.dk) |
| **Estonia** | Medical Devices Act–Riigi Teataja<br>1 January 2023<br><br>Estonian Medical Devices Act available In English: https://www.riigiteataja.ee/en/eli/ee/515032023005/consolide/current<br><br>Labelling and language requirements for medical devices \| Government installation profile (terviseamet.ee) | Estonian (§16 para 3 No.1 and No.3 for custom-made medical devices) | Estonian or English (§16 para 3 No.2)<br>NB! Language Act § 17 gives the professional user the right to demand information in Estonian. | Estonian or translated into Estonian (§ 32[4] No. 1) | Estonian or English (§16 para 5) | Estonian, initial FSN for urgent cases can be submitted in English (§ 27 (2)) | Not stated in the national law, but in practice we accept Estonian or English | Interpretation of the requirements in § 16 para 3: no certain requirement to translate GUI, but the manufacturer has to assess and establish a suitable way to inform the potential/intended user(s). | Interpretation of the requirements in § 16 para 3: no certain requirement to translate GUI, but the manufacturer has to assess and establish a suitable way to inform the potential/intended user(s). |
| **Finland** | Laki lääkinnällisistä laitteista 719/2021 (`Medical Devices Act´)<br>15 July 2021<br><br>In English: https://www.finlex.fi/en/laki/kaannokset/2021/en20210719.pdf | Finnish and Swedish (§5)<br><br>For Custom made MD: Finnish or Swedish, or both, depending on patient/customer need. | Finnish, Swedish or English. However, information necessary for '*safe use*'* must be in Finnish and Swedish. (§5).<br><br>*The manufacturer must | Finnish, Swedish and English (§5) | Finnish, Swedish or English (§5) | To be created in languages which are necessary for safety (§5) | Finnish, Swedish or English (§5) | Not specified, but GUI is in general treated similarly to IFU | Not specified, but GUI is in general treated similarly to IFU |

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| | | | determine, based on a risk assessment, which information is necessary for safe use. | | | | | | |
| **France** | Ordinance n° 2022-582 20 April 2022<br><br>Ordonnance n° 2022-582 du 20 avril 2022 portant adaptation du droit français au règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux - Légifrance (legifrance.gouv.fr)<br><br>(draft decree in progress)<br><br>The Use of the French Language \| economie.gouv.fr<br><br>Loi n° 94-665 du 4 août 1994 relative à l'emploi de la langue française - Légifrance (legifrance.gouv.fr) | French (Art. R5211-20) | French (Art. R5211-20) | French (draft decree in progress) | French (draft decree in progress) | French (draft decree in progress) | French | French based on the general safety and performance requirements 5 and 22 (no art. in the national law) | French or English based on general requirement 5 (no art. in the national law) taking into account the skills and the means available to the users and the influence resulting from variation that can be reasonably anticiped in the user's technique and environment |
| **Germany** | Gesetz zur Durchführung unionsrechtlicher | German (§ 8 para 2) | German or English or users | German (§ 8 para 3) | German or English (§ 8 para 1) | German (§73 para 1) | German or English (§ 17) | N/A | N/A |

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| | Vorschriften betreffend Medizinprodukte<br>28 April 2020<br><br>MPDG.pdf (gesetze-im-internet.de) | | language (in justified cases) (§ 8 para 2) | | | | | | |
| **Greece** | Directives 90/385/EEC (AIMDD) & 93/42/EEC (MDD)<br>national legislation decrees<br>ΔΥ8δ/Γ.Π.οικ. 130644 (ΦΕΚ Β' 2197/2009) &<br>ΔΥ8δ/Γ.Π.οικ.130648/ (ΦΕΚ Β' 2198/2009) | Greek<br>(Art. 4 para 4) | Greek<br>(MDD/AIMDD Art. 4 para 4)<br><br>For MDD, exceptionally in English (after CA approval) | | | | Greek and/or another EU language accepted from the NB (MDD Art. 11 para 12 & AIMDD Art.9 para 4) | | |
| **Hungary*** | https://www.ogyei.gov.hu/medical_devices | Hungarian* | Hungarian* | Hungarian* | | Hungarian* | Hungarian* | | |
| **Ireland** | Statutory Instrument No. 547/2017 – EU (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017<br>8 December 2017<br><br>S.I. No. 547 of 2017. | English language or English language and Irish language (No 5 (a)) | English language or English language and Irish language (No 5 (a)) | English language or English language and Irish language (No 5 (a)) | English language or English language and Irish language (No 5 (a)) | English language or English language and Irish language (No 5 (a)) | English language or English language and Irish language (No 5 (a)) | | |
| **Italy*** | **DECRETO LEGISLATIVO 5 agosto 2022, n. 137**<br>5 August 2022 | Italian (Art. 6)* | Italian (Art. 6)* | Italian and English (Art. 8)* | | Italian (Art. 10)* | Italian or another EU language accepted by the NB (Art. 11)* | | |

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| **Latvia** | Regulation No. 461 of the Cabinet of Ministers of the Republic of Latvia<br><br>"Medical Devices Regulations" adopted on 15 August 2023<br><br>Official Language Law<br>28 November 2017 | Latvian | Latvian or English if a medical device is intended to be used only in a health care facility and a consent of the health care facility is provided regarding use the foreign language | Latvian | Latvian | Latvian | Latvian | Latvian or English if an explanation of functions is available in the IFU | Latvian or English if a device is intended to be used only in a health care facility and a consent of the health care facility is provided |
| **Lithuania*** | XIII-2754 Lietuvos Respublikos sveikatos sistemos įstatymo Nr. I-552 2, 3, 16, 59-1, 59-2, 59-3, 59-4, 59-5... (e-tar.lt)<br>1 March 2020<br><br>Medical devices (under EU directives) \| State Accreditation Service for Health Care Activities under the Ministry of Health (lrv.lt) | Lithuanian* | Lithuanian* | | | Lithuanian* | | | |
| **Luxembourg** | Grand-Ducal Regulation of 11 August 1996 on medical devices<br><br>https://legilux.public.lu/eli/etat/leg/rgd/1996/08/11/n12/jo<br><br>Grand-Ducal Regulation of 5 February 1993 on | French, German or Luxembourgish (for MD) (Art. 4 para 4 of the 1996 regulation)<br><br>French or German (for AIMD) | French, German or Luxembourgish or English (for MD) (Art. 4 para 4 of the 1996 regulation)<br><br>French or German (for AIMD) | French or German for AIMD<br><br>(Art. 4 para 4 of the 1993 regulation)<br><br>French, German or Luxembourgish for MD | French or German and/or a language accepted by the notified body<br><br>Art. 9 para 4 of the 1993 regulation)<br><br>Art. 9 para 11 of the 1996 regulation) | French or German for AIMD<br><br>(Art. 4 para 4 of the 1993 regulation)<br><br>French, German or | French or German and/or a language accepted by the notified body<br><br>Art. 9 para 4 of the 1993 regulation) | French or German for AIMD<br><br>(Art. 4 para 4 of the 1993 regulation) | French, German or Luxembourgish or English (for MD) (Art. 4 para 4 of the 1996 regulation) |

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| | active Implantable medical devices<br><br>https://legilux.public.lu/eli/etat/leg/rgd/1993/02/05/n1/jo<br><br>medical-devices-EN.pdf (public.lu)The Luxembourgish legislator expects that the patient or user receive information in a language they understand | (Art. 4 para 4 of the 1993 regulation) | (Art. 4 para 4 of the 1993 regulation) | (Art. 4 para 4 of the 1996 regulation) | | Luxembourgish for MD<br><br>(Art. 4 para 4 of the 1996 regulation) | Art. 9 para 11 of the 1996 regulation) | French, German or Luxembourgish for MD<br><br>(Art. 4 para 4 of the 1996 regulation) | French or German (for AIMD) (Art. 4 para 4 of the 1993 regulation) |
| **Malta** | SUBSIDIARY LEGISLATION 458.59 MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC MEDICAL DEVICES PROVISION ON THE MALTESE MARKET REGULATIONS<br>4 August 2020<br><br>Medicines Authority (gov.mt) | Maltese and/or English | Maltese and/or English | Maltese and/or English | Maltese and/or English | Maltese and/or English | Maltese and/or English | Maltese and/or English | Maltese and/or English |
| **The Netherlands** | Regeling medische hulpmiddelen<br><br>26 May 2022<br><br>BWBR0043450 (overheid.nl) | Dutch<br>(Art. 1 para 1) | Dutch or English<br>(Art. 1 para 2) | Dutch<br>(Art. 1 para 1) | Dutch or English<br>(Art. 1 para 3) | Dutch or English<br>(Art. 1 para 3) | Dutch or English (Art. 1 para 3) | | |
| **Poland** | USTAWA z dnia 7 kwietnia 2022 r. o wyrobach medycznych<br>7 April 2022 | Polish<br>(Art. 12 para 1) | Polish or English<br>(Art. 12) | Polish (art. 12 para 4)+ art. 12 para 3 ustawa o prawach pacjenta | Polish – lay user<br>(Art. 12 para 1)<br>English – professional user | Polish (art. 49 para 3) | Polish or English (Art. 28 para 9) | Polish or English but IFU in Polish | English (art. 12 para 5) |

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| | https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20220000974 | | | z 6 listopada 2008 r.– https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20090520417 | (Art. 12 para 2) | | | (art. 12 par. 1, 2) With the exception of devices intended for use in life and health emergencies | |
| **Portugal** | Decree-Law 145/2009 (tretas.org)<br>17 June 2009<br>The national legal framework for the MDR is still under legislative circuit – this will include language requirements | Portuguese (Art. 5 para 6) | Portuguese (Art. 5 para 6) | Portuguese*<br>*The publication of the national legal framework for the MDR is still pending. | Portuguese (although English is accepted - current procedure)*<br>*The publication of the national legal framework for the MDR is still pending. | Portuguese | Portuguese (although English is accepted - current procedure)<br>*The publication of the national legal framework for the MDR is still pending. | | |
| **Romania*** | http://legislatie.just.ro/Public/DetaliiDocument/243191<br>11 June 2021 | Romanian (Art. 3 para 1)* | Romanian or English (written consent of healthcare professional needed) (Art. 3 para 2)* | | Romanian or English (Art. 3 para 7)* | | Romanian or English (with approval of the CA)* | | |
| **Slovakia** | Act Nr.362/2011 Coll. on Drugs and Medical Devices<br><br>Act Nr. 270/1995 Coll. on Offical Language of the Slovak Republic | Slovak (Art. 110 b para 1)<br>Label in ENG if intended for a professional use | Slovak (Art. 110 b para 1) | Slovak (Art. 110 b para 1) | Slovak or English | English | language accepted by the NB (mostly SVK or ENG) | Slovak | English has to be explained in the Slovak IFU |
| **Slovenia** | Since the national legislation concerning the Regulations is not | Slovene; | Slovene; | Slovene | Slovene | Slovene | | Slovene | Slovene; |

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| | prepared yet, the Medical Devices act is still in use, from article 33 of Slovenian Medical Devices Act (Official Gazette RS, nr. 98/2009, Zakon o medicinskih pripomočkih (ZMedPri) (pisrs.si) ; available only in slovene language ):<br><br>(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.<br><br>The same applies for labelling and packaging. | | For professional use: the instructions for use can be written in the language understandable for the user. (Normally English is acceptable | | | | | | For professional use: the instructions for use can be written in the language understandable for the user. (Normally English is acceptable |
| **Spain** | Real Decreto 192/2023, de 21 de marzo, por el que se regulan los productos sanitarios<br>22 March 2023 | Spanish (art. 5.2) | Spanish (art. 5.2) | Spanish (art 36.6) | | Spanish (art 35.6) | | | |

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| | BOE-A-2023-7416 | | | | | | | | |
| **Sweden** | Förordning (2021:631) med kompletterande bestämmelser till EU:s förordningar om medicintekniska produkter \| Sveriges riksdag (riksdagen.se)<br><br>Language requirements \| Swedish Medical Products Agency (lakemedelsverket.se) | Swedish<br>(3 chapter 1 §) | Swedish<br>(3 chapter 1 §) | Swedish or English<br>(3 chapter 1 §, second paragraph) | Swedish or English<br>(3 chapter 2 §) | Swedish<br>(3 chapter 1 §) | Swedish or a language accepted by the notified body<br>(3 chapter 2 §, second paragraph | See website Language requirements \| Swedish Medical Products Agency (lakemedelsverket.se) | See website Language requirements \| Swedish Medical Products Agency (lakemedelsverket.se) |
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| **Iceland** | Act on Medical Devices No. 132/2020<br>8 December 2020<br><br>X2020132.dvi (government.is)<br><br>Regulation on IFU with Medical Devices 630/2022<br>https://island.is/reglugerdir/nr/0630-2022 | Icelandic, allowed to be in English or Nordic language except Finnish for class I and IIa<br>(Art. 12) | Icelandic or English<br>(Art. 12) | Icelandic (Art. 19) | Icelandic or English | Icelandic or English | English | Icelandic, allowed to be in English or Nordic language except Finnish for class I and IIa | Icelandic or English |
| **Liechtenstein** | Verordnung über den Verkehr mit Medizinprodukten im Europäischen Wirtschaftsraum<br>27 April 2021<br><br>EWR-MepV \| Lilex - Gesetzesdatenbank des Fürstentum Liechtenstein | German<br>(Art. 10 para 1) | German or English, if certain requirements are met (Art. 10 para 2) | German<br>(Art. 11 para 1) | German or English<br>(Art. 10 para 4) | German<br>(Art. 10 para 3) | | | |

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| **Norway** | Medical Device Regulations - Chapter III. Supplementary national language provisions - Lovdata | Norwegian (Chapter III Sec. 6) | Norwegian (Chapter III Sec. 6) | Norwegian (Chapter III Sec. 13) | English or Norwegian (Chapter III Sec. 8) | Norwegian (Chapter III Sec. 12) | English (Chapter III Sec. 7) | Norwegian (Chapter III Sec. 6) Except: Symbols such as "On", "Off", "Load", "Enter", "Page up". | Norwegian (Chapter III Sec. 6) Except: Symbols such as "On", "Off", "Load", "Enter", "Page up". |
| **Turkey** | Law No. 7223 on Product Safety and Technical Regulations<br><br>*Dated 02.06.2021 and numbered 31499* Medical Device Regulation (TR-MDR)<br><br>Circular No. 2022/1 on medical devices | Turkish (TR-MDR Art 10 para 11) and Law No. 7223 Art 7 (1)(ğ) ) | Turkish ( TR- MDR Art 10 para 11 and Law No. 7223 Art para 7 (1)(ğ) )<br><br>Exception: Label may be in English (with approval of the CA) in accordance with Section E, point 2 of Circular No. 2022/1 | Turkish and, if necessary, English ( TR-MDR Art 18 para 2) | Turkish ( TR-MDR Art 19 para 1) | Turkish (TR-MDR Art 87 para 8(a) ) | Turkish (TR-MDR Art 52 para 11 ) | Turkish | Turkish *or* English provided that IFU are presented in Turkish |

**Other language requirements**: For the Summary of Safety and Clinical Performance of a device (SSCP), Art. 32 MDR, please see the ***MDCG-2019-9 Rev.1 Guidance Document***, that recommends the SSCP to "*be written in a way that is clear to the intended user and, if relevant, to the patient (see* MDR, Annex II (2), Article 10 (11)*), the SSCP should be translated into the languages accepted in the Member States where the device is envisaged to be sold"(p. 6).*

*Recent information is not available for the country