



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 (1) MDR)	Declaration of conformity (Art 19 (1) MDR)	Field safety notice (Art. 89 (8) MDR)	Documents for conformity assessment (Art. 52 (12))	(Graphic) user interface (e.g. Apps)	
		Patient/lay user	Professional user					Patient /lay user	Professio nal user
Austria*	Bundesgesetz betreffend Medizinprodukte 30 June 2021 Medizinproduktegesetz- 2021	German (§7 para 1)*	German or English (§7 para 1)*	German (§7 para 4)*	German (§7 para 2)*	German (§7 para 6)*	German or English (§7 para 7 No. 1)*		

Belgium	Wet betreffende medische hulpmiddelen 18 January 2021 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) 12 June 2007 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 22 November 2018 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 Regulatory Information 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

	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 1 March 2021 375/2022 Sb. Zákon o zdravotnických prostředcích a diagnostických zdravotnických prostředcích in vitro (zakonyprolidi.cz) 7 December 2022 https://www.niszp.cz/sites/default/files/dokumenty/ZoZPaIVD_AJ%20verze.pdf	Czech (§8 para 2)	Czech (§8 para 2)	Czech (§8 para 2)	Czech, Slovak or English (§8 para 1)	Czech (§ 8 para 2)	Czech, Slovak or English (§ 8 para 1)	Czech	Czech or English
Denmark	Executive Order no. 837 of 20 June 2023 on Medical Devices etc. Bekendtgørelse om medicinsk udstyr m.v. (retsinformation.dk) Language requirement for information about medical devices (laegemiddelstyrelsen.dk)	Danish (Chapter II § 3)	Danish; English possible upon request (Chapter II § 3 para 2)	Danish, exception English (Chapter II § 4 para 2)	English, Danish in specific cases (Chapter II § 6)			https://www.retsinformation.dk/eli/retsinfo/2021/984 Danish Guidance, section 2 Language requirement for information	https://www.retsinformation.dk/eli/retsinfo/2021/984 Danish Guidance, section 2 Language requirement for information

								n about medical devices(laegemiddelstyrelsen.dk)	n about medical devices(laegemiddelstyrelsen.dk)
Estonia	Medical Devices Act–Riigi Teataja 1 January 2023 Estonian Medical Devices Act available In English: https://www.riigiteataja.ee/en/eli/ee/515032023005/consolide/current 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) 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') 15 July 2021 In English: https://www.finlex.fi/en/laki/kaannokset/2021/en20210719.pdf	Finnish and Swedish (§5) 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). *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

			determine, based on a risk assessment, which information is necessary for safe use.						
France	Ordonnance n° 2022-582 20 April 2022 <u>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)</u> (draft decree in progress) <u>The Use of the French Language economie.gouv.fr</u> <u>Loi n° 94-665 du 4 août 1994 relative à l'emploi de la langue française - Légifrance (legifrance.gouv.fr)</u>	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 anticipated 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

	Vorschriften betreffend Medizinprodukte 28 April 2020 MPDG.pdf (gesetze-im-internet.de)		language (in justified cases) (§ 8 para 2)						
Greece	Directives 90/385/EEC (AIMDD) & 93/42/EEC (MDD) national legislation decrees ΔΥ8δ/Γ.Π.οικ. 130644 (ΦΕΚ Β' 2197/2009) & ΔΥ8δ/Γ.Π.οικ.130648/ (ΦΕΚ Β' 2198/2009)	Greek (Art. 4 para 4)	Greek (MDD/AIMDD Art. 4 para 4) 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 8 December 2017 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 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)*		

Latvia	Regulation No. 461 of the Cabinet of Ministers of the Republic of Latvia "Medical Devices Regulations" adopted on 15 August 2023 Official Language Law 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*	<u>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)</u> 1 March 2020 <u>Medical devices (under EU directives) State Accreditation Service for Health Care Activities under the Ministry of Health (lr.v.lt)</u>	Lithuanian*	Lithuanian*			Lithuanian*			
Luxembourg	Grand-Ducal Regulation of 11 August 1996 on medical devices https://legilux.public.lu/eli/etat/leg/rqd/1996/08/11/n12/jo Grand-Ducal Regulation of 5 February 1993 on	French, German or Luxembourgish (for MD) (Art. 4 para 4 of the 1996 regulation) French or German (for AIMD)	French, German or Luxembourgish or English (for MD) (Art. 4 para 4 of the 1996 regulation) French or German (for AIMD)	French or German for AIMD (Art. 4 para 4 of the 1993 regulation) French, German or Luxembourgish for MD	French or German and/or a language accepted by the notified body Art. 9 para 4 of the 1993 regulation) Art. 9 para 11 of the 1996 regulation)	French or German for AIMD (Art. 4 para 4 of the 1993 regulation) French, German or	French or German and/or a language accepted by the notified body Art. 9 para 4 of the 1993 regulation)	French or German for AIMD (Art. 4 para 4 of the 1993 regulation)	French, German or Luxembourgish or English (for MD) (Art. 4 para 4 of the 1996 regulation)

	active Implantable medical devices https://legilux.public.lu/eli/etat/leg/rgd/1993/02/05/n1/jo 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 (Art. 4 para 4 of the 1996 regulation)	Art. 9 para 11 of the 1996 regulation)	French, German or Luxembourgish for MD (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 4 August 2020 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 26 May 2022 BWBR0043450 (overheid.nl)	Dutch (Art. 1 para 1)	Dutch or English (Art. 1 para 2)	Dutch (Art. 1 para 1)	Dutch or English (Art. 1 para 3)	Dutch or English (Art. 1 para 3)	Dutch or English (Art. 1 para 3)		
Poland	USTAWA z dnia 7 kwietnia 2022 r. o wyrobach medycznych 7 April 2022	Polish (Art. 12 para 1)	Polish or English (Art. 12)	Polish (art. 12 para 4)+ art. 12 para 3 ustawa o prawach pacjenta	Polish – lay user (Art. 12 para 1) 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)

	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=wd u20090520417	(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) 17 June 2009 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* *The publication of the national legal framework for the MDR is still pending.	Portuguese (although English is accepted - current procedure)* *The publication of the national legal framework for the MDR is still pending.	Portuguese	Portuguese (although English is accepted - current procedure) *The publication of the national legal framework for the MDR is still pending.		
Romania*	http://legislatie.just.ro/Public/DetaliuDocument/243191 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 Act Nr. 270/1995 Coll. on Official Language of the Slovak Republic	Slovak (Art. 110 b para 1) 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;

	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): (5) The instructions for use must be written in the <i>Slovene language</i>, 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. 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 22 March 2023	Spanish (art. 5.2)	Spanish (art. 5.2)	Spanish (art 36.6)		Spanish (art 35.6)		

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

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 <i>Dated 02.06.2021 and numbered 31499</i> Medical Device Regulation (TR-MDR) 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)) <u>Exception:</u> 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 should be translated into the language of the Member State in which the device is placed on the market (Annex II (2), Article 10 (11)), the

*Recent information i



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



器械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
器械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE