EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Devices

MDR - Language requirements for manufacturers - Rev. 2 (August 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. It is updated when Member State authorities inform about changes. 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.

Revision history

Date	**Action**
January 2024	Initial issue
March 2024	1st update (Rev. 1) - France - documents for conformity assessment: addition of English (for certain parts)
August 2024	2nd update (Rev. 2) - Romania - updated and more accurate information

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)**	
		Patient/lay user	**Professional user**					**Patient /lay user**	**Professional user**
EU Member States									
Austria*	Bundesgesetz betreffend Medizinprodukte 30 June 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		

	RIS - Medizinprodukte gesetz 2021 - Bundesrecht konsolidiert, Fassung vom 12.09.2024 (bka.gv.at)						(§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 o provedbi Uredbe (EU) 2017/745 o medicinskim proizvodima i Uredbe (EU) 2017/746 o in vitro dijagnostičkim medicinskim proizvodima - 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) Law 30 (I)/2002 relating to the Basic Requirements of Certain Categories of Products Basic Requirements (Medical Devices) Regulations 598/2003	Greek	Greek or English	Greek or English	Greek or English	Greek or English	Greek or English	Greek	Greek or English
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 ZoZPaIVD_AJ verze.pdf (niszp.cz)	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/2021/9840 Danish Guidance, section 2 Language requirement for information about medical	https://www.retsinformation.dk/eli/retsinfo/2021/9840 Danish Guidance, section 2 Language requirement for information about medical

								devices(laegemiddelstyrelsen.dk)	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: en20210719.pdf (finlex.fi)	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 determine, based on a risk assessment, which information is necessary for safe use	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
France	Ordonnance n° 2022-582 du 20 avril 2022 portant adaptation du droit	French (Art. R5211-20)	French (Art. R5211-20)	French (draft decree in progress)	French (draft decree in progress)	French (draft decree in progress)	French or English (for certain parts)	French based on the general	French or English based on

	français au règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux - Légifrance (legifrance.gouv.fr) 20 April 2022 (draft decree in progress) L'emploi de la langue française | economie.gouv.fr Loi n° 94-665 du 4 août 1994 relative à l'emploi de la langue française - Légifrance (legifrance.gouv.fr)						(draft decree in progress)	safety and performance requirements 5 and 22 (no art. in the national law)	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 Vorschriften betreffend Medizinprodukte 28 April 2020 MPDG.pdf (gesetze-im-internet.de)	German (§ 8 para 2)	German or English or users' language (in justified cases) (§ 8 para 2)	German (§ 8 para 3)	German or English (§ 8 para 1)	German (§73 para 1)	German or English (§ 17)	N/A	N/A
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	S.I. No. 547/2017 - European Union (Medical Devices and In Vitro	English language or English	English language or English	English language or English	English language or English	English language or English	English language or English		

	Diagnostic Medical Devices) Regulations 2017 (irishstatutebook.ie) 8 December 2017	language and Irish language (No 5 (a))	language and Irish language (No 5 (a))	language and Irish language (No 5 (a))	language and Irish language (No 5 (a))	language and Irish language (No 5 (a))	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*	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) 1 March 2020 Medicinos priemonės (pagal ES direktyvas) - Valstybinė akreditavimo sveikatos priežiūros veiklai tarnyba prie Sveikatos apsaugos ministerijos (lrv.lt)	Lithuanian*	Lithuanian*			Lithuanian*			
Luxembourg	Grand-Ducal Regulation of 11 August 1996 on medical devices	French, German or Luxembourgish (for MD)	French, German or Luxembourgish or	French or German for AIMD	French or German and/or a language accepted by the notified body	French or German for AIMD	French or German and/or a language accepted by	French or German for AIMD	French, German or Luxembourgish or

	https://legilux.public.lu/eli/etat/leg/rgd/1996/08/11/n12/jo Grand-Ducal Regulation of 5 February 1993 on 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 1996 regulation) French or German (for AIMD) (Art. 4 para 4 of the 1993 regulation)	English (for MD) (Art. 4 para 4 of the 1996 regulation) French or German (for AIMD) (Art. 4 para 4 of the 1993 regulation)	(Art. 4 para 4 of the 1993 regulation) French, German or Luxembourgish for MD (Art. 4 para 4 of the 1996 regulation)	Art. 9 para 4 of the 1993 regulation) Art. 9 para 11 of the 1996 regulation)	(Art. 4 para 4 of the 1993 regulation) French, German or Luxembourgish for MD (Art. 4 para 4 of the 1996 regulation)	the notified body Art. 9 para 4 of the 1993 regulation) Art. 9 para 11 of the 1996 regulation)	(Art. 4 para 4 of the 1993 regulation) French, German or Luxembourgish for MD (Art. 4 para 4 of the 1996 regulation)	English (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
Netherlands	Regeling medische hulpmiddelen 26 May 2022 wetten.nl - Regeling - Regeling medische hulpmiddelen - 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 (art. 12 par.	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=wdu20090520417	(Art. 12 para 2)			1, 2) With the exception of devices intended for use in life and health emergencies	
Portugal	https://diariodarepublica.pt/dr/detalhe/decreto-lei/145-2009-494558 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	Emergency Government Ordinance (EGO) no 46/11.06.2021 at https://legislatie.just.ro/Public/DetaliiDocument/243191 and Minister of Health Order (MHO) no 3539/09.12.2022 at https://www.anm.ro/_/DM/LEGISLATIE/Ordin%203539-2022.pdf	Romanian (Art. 3 para 1)	Romanian or English with CA's approval based on written consent of healthcare professional) (Art. 3 para 2) English, with CA's approval (free of charge) according to procedure from Chapter V	Romanian (Art. 5 para 3)	Romanian or English (Art. 3 para 7)	Romanian or English (Art. 9 para 7), for professional users only, English is accepted on request (Art. 9 para 8)	Romanian or English (with CA's approval) as in (Art. 3 para 4)	Romanian (Art. 3 para 3)	Romanian (Art. 3 para 3) or English in justified cases, based on written consent of the user
Slovakia	Act Nr.362/2011 Coll. on Drugs and Medical Devices	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

	Act Nr. 270/1995 Coll. on Official Language of the Slovak Republic								
Slovenia	Since the national legislation concerning the Regulations is not 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 *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. The same applies for labelling and packaging	Slovene	Slovene For professional use: the instructions for use can be written in the language understandable for the user (normally English is acceptable)	Slovene	Slovene	Slovene		Slovene	Slovene 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 BOE-A-2023-7416	Spanish (art. 5.2)	Spanish (art. 5.2)	Spanish (art 36.6)		Spanish (art 35.6)			
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)
EEA Countries									
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"
CU Country									
Türkiye	Law No. 7223 on Product Safety and Technical Regulations Dated 02.06.2021 and numbered 31499 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)) 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