EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Devices

IVDR – national language requirements for manufacturers Rev. 1 (March 2024)

Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) 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 IVDR and the provisions of the Member States implementing the IVDR 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)

Country	**Relevant legal provision (reference and hyperlink to official publication)**	**Label/IFU (Art. 10 (10), Annex I, section 20, IVDR)**		**Declaration of conformity (Art. 17 (I) IVDR**	**Field safety notice (Art. 84 (8) IVDR)**	**Documents for conformity assessment (Art. 48 (12) IVDR)**	**(Graphic) user interface (e.g. Apps)**	
		information accompanying the device	**devices for self-testing or near-patient testing**				**Patient/lay user**	**Professional user**
Austria*	Bundesgesetz betreffend Medizinprodukte 30 June 2021	German (§7 para 1)*		German* (§7 para 2)	German* (§7 para 6)	German or English* (§7 para 7 No. 2)		

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	Medizinproduktegesetz-2021	German or English, if device is intended for a professional user (§7 para 1)						
Belgium	Wet betreffende medische hulpmiddelen voor in-vitrodiagnostiek 15 June 2022 law IVD 15_06_22.pdf (famhp.be)	French and Dutch and German. Or in English if device is intended exclusively for a professional user (Art. 9 §1)	French and Dutch and German (Art. 9 §1)	French, Dutch, German or English (Art. 12)	French and Dutch and German; English is allowed in case user is a healthcare professional (Art. 64)	French, Dutch, German or English (Art. 19)	Considered as the Label/IFU information: French and Dutch and German (Art. 9 §1)	Considered as the Label/IFU information: French and Dutch and German. Or in English if device is intended exclusively for a professional user (Art. 9 §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)						
Croatia	Act implementing Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic	Croatian and/or English (declaration/agreement of professional	Croatian (Art. 30) except if the near patient testing is	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	Any GUI elements linked to performance or safety

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	medical devices 22 November 2018 Zakon.hr	user needed) (Art. 30). “or” is to be read as without prejudice to Art. 10(p.10) IVDR – information supplied should be clearly comprehensible to the intended user	performed by a professional user				should follow the same rules as label/IFU	should follow the same rules as label/IFU
Cyprus	Cyprus Medical Devices Authority Regulatory Information Ιατρικές Υπηρεσίες (moh.gov.cy)	Greek Greek or English, if intended for a professional user	Greek or English	Greek or English	Greek or English	Greek or English	Greek	Greek or English
Czech Republic	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, Slovak or English (§ 8 para 1)	Czech (§ 8 para 2)	Czech, Slovak or English (§ 8 para 1	Czech	Czech or English

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
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 (Chapter II § 3 para 3)	English, Danish in specific cases (Chapter II § 6)				
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	Estonian (§16 para 3 No.1)	Estonian or English, if device is intended for a professional user (§16 para 3 No.2) NB! Language Act § 17 gives the professional user the right to demand information in Estonian	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	For professional users: Finnish, Swedish or English. However,	**For devices for self-testing**: Finnish *and* Swedish (§5)	Finnish or 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	Not specified, but GUI is in general treated

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	In English: https://www.finlex.fi/en/laki/kaannokset/2021/en20210719.pdf	information necessary for '*safe use*'* must be in Finnish and Swedish. For laymen: Finnish *and* Swedish (§5) *The manufacturer must determine, based on a risk assessment, which information is necessary for safe use.	**For devices for near-patient use**: as for other devices for professional use. Information necessary for safe use must be in Finnish and Swedish. The manufacturer must determine, based on a risk assessment, which information is necessary for safe use.				similarly to IFU	similarly to IFU
France	Ordinance n° 2022-1086 – 20 july 2022 Ordonnance n° 2022-1086 du 29 juillet 2022 portant adaptation du droit français au règlement (UE)	French (Art. R5221-14). Draft change in progress	French (Art. R5221-14). Draft change in progress	French (draft decree in progress)	French (draft decree in progress)	French or English (for certain parts) (draft decree in progress)	French based on the general safety and performance requirements 5 IVDR (no	French or English based on general requirement 5 (no art. in the national law)

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic in vitro (https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000046113837) The Use of the French Language | economie.gouv.fr Loi n° 94-665 du 4 août 1994 relative à l'emploi de la langue française - Légifrance (legifrance.gouv.fr)						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 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, when device is intended for a professional user (§ 8 para 2)	German (§ 8 para 2) German or English or users language in justified cases, when device is intended for a professional user (§ 8 para 2)	German or English (§ 8 para 1)	German (§73 para 1)	German or English (§ 17)	N/A	N/A

Country	Relevant legal provision (reference and hyperlink to official publication)	Label/IFU (Art. 10 (10), Annex I, section 20, IVDR)		Declaration of conformity (Art. 17 (I) IVDR	Field safety notice (Art. 84 (8) IVDR)	Documents for conformity assessment (Art. 48 (12) IVDR)	(Graphic) user interface (e.g. Apps)	
		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
Greece	Directive 98/79/EC, national legislation decree Αριθ. ΔΥ8δ/οικ.3607/892 (ΦΕΚ Β' 1060/10.8.2001)	Greek (Article 4 para 4) exceptionally only the label in English, if device is intended for a professional user (after CA approval). Software for IVDs is exempted from the requirements of this paragraph.	Greek			Greek and/or another EU language accepted from the NB (Art. 9 para 11)		
Hungary*	https://www.ogyei.gov.hu/medical_devices 8/2003. (III. 13.) ESzCsM rendelet az in vitro diagnosztikai orvostechnikai eszközökről - Hatályos Jogszabályok Gyűjteménye (jogtar.hu)	Hungarian*	Hungarian*	Hungarian*	Hungarian*	Hungarian*		
Ireland	Statutory Instrument No. 547/2017 – EU (Medical Devices and In Vitro	English language or English	English language or English	English language or English language and Irish language (No 5 (b))	English language or English language and Irish language (No 5 (b))	English language or English language and Irish language (No 5 (b))		

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	Diagnostic Medical Devices) Regulations 2017 8 December 2017 Link: S.I. No. 547 of 2017.	language and Irish language (No 5 (b))	language and Irish language (No 5 (b))		(No 5 (b))			
Italy	**DECRETO LEGISLATIVO 5 agosto 2022, n. 138** 5 August 2022 https://www.gazzettaufficiale.it/eli/id/2022/09/13/22G00146/sg	Italian (Art. 6)	Italian (Art. 6)		Italian (Art. 13)	Italian or another EU language accepted by the NB (Art. 8)		
Latvia	Regulation No. 582 of the Cabinet of Ministers of the Republic of Latvia "*In vitro* Diagnostic Medical Devices Regulations" adopted on 10 October 2023 Official Language Law 28 November 2017	Latvian or English if an IVD medical device is intended to be used only in a health care facility by suitably qualified and trained medical personnel 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 an IVD 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	Lithuanian*	Lithuanian*		Lithuanian*			

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	2, 3, 16, 59-1, 59-2, 59-3, 59-4, 59-5... (e-tar.lt) 1 March 2020 Medical devices (under EU directives) | State Accreditation Service for Health Care Activities under the Ministry of Health (lrv.lt)							
Luxembourg	Grand-Ducal Regulation of 24 July 2001 regarding in vitro diagnostic medical devices https://data.legilux.public.lu/filestore/eli/etat/leg/rgd/2001/07/24/n1/jo/fr/html/eli-etat-leg-rgd-2001-07-24-n1-jo-fr-html.html medical-devices-EN.pdf (public.lu) The Luxembourgish legislator expects that the patient or user receive information in a language they understand	French, German or Luxembourgish English is accepted, if device is intended for a professional user (Art. 4 para 4 of the 2001 regulation)	French, German or Luxembourgish (Art. 4 para 4 of the 2001 regulation)	French or German and/or a language accepted by the notified body Art. 7 para 11 of the 2001 regulation)	French, German or Luxembourgish (Art. 4 para 4 of the 2001 regulation)	French or German and/or a language accepted by the notified body Art. 7 para 11 of the 2001 regulation)	French, German or Luxembourgish (Art. 4 para 4 of the 2001 regulation)	French, German or Luxembourgish. English is accepted, if device is intended for a professional user
Malta	SUBSIDIARY LEGISLATION 458.59	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

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC MEDICAL DEVICES PROVISION ON THE MALTESE MARKET REGULATIONS 4 August 2020 Medicines Authority (gov.mt)							
The Netherlands	Regeling medische hulpmiddelen 26 May 2022 wetten.nl -BWBR0043450 (overheid.nl)	Dutch (Art. 1 para 1) Dutch or English, if device is intended for a professional user	Self-tests: Dutch Near-patient tests: Dutch or English (if used by a professional)	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 https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20220000974	Polish (Art. 12 para 1) Polish or English, if device is intended for a professional user	Self-tests: Polish Near-patient tests: Polish or English (if used by a professional)	Polish – lay user (Art. 12 para 1) English – professional user (Art. 12 para 2)	Polish (art. 49 para 3)	Polish or English (Art. 28 para 9)	Polish or English but IFU in Polish (art. 12 par. 1, 2) With the exception of devices intended for use in life and health emergencies	English (art. 12 para 5)

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
Portugal	Decree-Law 189/2000 12 August 2000 EN Translation: In vitro diagnostic medical devices (IVDDs) and applicable legislation - INFARMED, I.P. The publication of the national legal framework for the IVDR is still pending	Portuguese	Portuguese	Portuguese (although or English is accepted -current procedure)* *The publication of the national legal framework for the MDR is still pending.	Portuguese	Portuguese (although or English is accepted - current procedure)* *The publication of the national legal framework for the MDR is still pending.		
Romania*	ORDONANȚĂ DE URGENȚĂ nr. 137 din 12 octombrie 2022 13 October 2022 Portal Legislativ (just.ro)	Romanian* (Art. 3 para 1) Romanian or English, if intended for a professional user; (written consent of healthcare professional needed)	Romanian*	Romanian or English (Art. 3 para 9)*	English and Romanian* (Art. 7 para 7) Upon request of health professionals only English, if exclusively used by health professionals (Art. 7 para 8)	Romanian*		
Slovakia	Act Nr.362/2011 Coll. on Drugs and Medical Devices Act Nr. 270/1995 Coll. on Offical 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 or English	English	language accepted by the NB (mostly SVK or ENG)	Slovak	English has to be explained in the Slovak IFU

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
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	Slovene; For professional use: the instructions for use can be written in the language understandable for the user. (Normally English is acceptable)	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; For professional use: the instructions for use can be written in the language understandable for the user. (Normally English is acceptable)

Country	Relevant legal provision (reference and hyperlink to official publication)	Label/IFU (Art. 10 (10), Annex I, section 20, IVDR)		Declaration of conformity (Art. 17 (I) IVDR	Field safety notice (Art. 84 (8) IVDR)	Documents for conformity assessment (Art. 48 (12) IVDR)	(Graphic) user interface (e.g. Apps)	
		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	instructions for use can be written in the language understandable for the user. The same applies for labelling and packaging.							
Spain	Real Decreto 1662/2000, por el que se regulan los productos sanitarios de diagnóstico in vitro, del 29 de septiembre. Real Decreto 1662/2000, de 29 de septiembre, sobre productos sanitarios para diagnóstico "in vitro". (boe.es)	Spanish	Spanish		Spanish (according with *MEDDEV 2 12-1 rev. 8 Vigilance* since Spanish is the language accepted by the AEMPS)			
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 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)

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
Iceland	Act on Medical Devices No. 132/2020 8 December 2020 Iceland-Act-on-Medical-Devices-1322020-of-8-December-2020.pdf (mastermindtranslations.co.uk) https://island.is/reglugerdir/nr/0630-2022 EN Translation: X2020132.dvi (government.is)	Icelandic (Art. 12)	Icelandic	Icelandic or English	Icelandic or English	English	Icelandic	Icelandic/ English
Liechtenstein	Verordnung über den Verkehr mit In-vitro-Diagnostika im Europäischen Wirtschaftsraum 3 May 2022 EWR-IvDV | Lilex - Gesetzesdatenbank des Fürstentum Liechtenstein	German (Art. 11 para 1) German or English, if intended for a professional user and certain requirements are met (Art. 11 para 2)	German (Art. 11 para 5)	German or English (Art. 11 para 4)	German (Art. 11 para 3)			
Norway	Medical Device Regulations - Lovdata 9 May 2021	Norwegian (Chapter III Sec. 6)	Norwegian	English or Norwegian (Chapter III Sec. 8)	Norwegian (Chapter III Sec. 12)	English (Chapter III Sec. 7)		

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		information accompanying the device	devices for self-testing or near-patient testing				Patient/lay user	Professional user
	Medical Device Regulations - Chapter III. Supplementary national language provisions - Lovdata 12 May 2021			(Exceptions possible, see Sec. 15)				
Turkey	Law No. 7223 on Product Safety and Technical Regulations Dated 02.06.2021 and numbered 31499 Regulation on in vitro Diagnostic Medical Devices (TR-IVDR) Circular No. 2022/1 on medical devices	Turkish (TR-IVDR Art 11(10) and Law No. 7223 Art 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/	Turkish (TR-IVDR Art 11(10))	Turkish (TR-IVDR Art 18 (1))	Turkish (TR-IVDR Art 84 (8)(a))	Turkish (TR-IVDR Art 50 (12))	Turkish	Turkish or English provided that IFU are presented in Turkish.

Other language requirements: For the Summary of Safety and Performance of a device (SSP), Art. 29 IVDR, please see the ***MDCG-2022-9 Template***.

*Recent information is not available for the country