Informal collection of national requirements in EU

Within the transition into (EU) 2017/745 MDR, some EU27 member states will implement national laws and additional requirements. The table below gives an overview of the current status.

Important: This table is a collection of informal information and is surly not complete and up-to-date. Whenever you notice an error on an outdated information, just let me know and I'll update.

If you want, I can add your email as reference in the table. If no source is given, it's me to be blamed for the information.

Looking forward to lots of feedback……

Country	Language requirement for professional use	Link to national law	Specifics	Source
Austria	german			
Belgium	french, dutch, german	http://www.ejustice.just.fgov.be/eli/arrete/2021/05/12/2021041390/moniteur	Three national languages (=Dutch, French, German): Art. 9. §1 "Pursuant to Article 10(11) of Regulation 2017/745, manufacturers shall accompany devices made available to the user or patient on Belgian territory with the information referred to in Section 23 of Annex I to Regulation 2017/745 in the three national languages. By way of exception, for devices whose users are exclusively health professionals, this information may be provided in English. In this case, however, the user may require the manufacturer to provide this information in the language of his choice."	https://www.linkedin.com/in/dr-uwe-boetcher-b10799a7/
Bulgaria	bulgarian			
Croatia	croatian			
Cyprus	greek			

National Implementation of MDR

Czech republic	czech	ongoing	In the Czech Republic there is a new national law implementing MDR under preparation but none is available for public. Will keep monitoring the situation	https://www.linkedin.com/in/daniel-tokar-b85216102/
Denmark	danish			
Estonia	estonian			
Finnland	finnish/swedish			
France	french			
Germany	german	http://www.gesetze-im-internet.de/mpdg/	Medical Device Consultant needed, Distributors may need to register. Manufacturer of implantable custom made class III and single use refurbishing must register	§8 gives more details
Greece	greek	ongoing	In Greece, in a recent training conference re: MDR in Athens, organized by Pharmacist's Union, the Competent Authority representatives announced that they are working on a transposing document, (expected probably spring 2020). In any case, I will trace this and inform accordingly. In Greece, there is also a legal requirement for Importers and Distributors of MD to be audited by NBs for their activities, (in a light form of GDPs), and copies of these Attestations of Compliance are copied to Competent Authority (DY8/1348/2004, OJ 32B, in Greek)	https://www.linkedin.com/in/george-melachrinos-297b7623/
Hungary	hungarian			
Iceland	english			
Irleland	english			
Italy	italian			
Latvia	latvian			
Liechtenstein	german			
Lithuania	lithuanian			
Luxembourg	french, dutch			
Malta	english			
Netherlands	dutch	ongoing	ongoing	https://medicaldeviceslegal.com/2019/05/12/national-mdr-and-ivdr-implementation-news-netherlands-implementation-decree-consultation/

National Implementation of MDR

Norway	norwegian			
Poland	polish			
Portugal	portuguese			
Romania	romanian	no changes	In Romania there are no changes for the moment in the local legislation. In any case, according to the existing local legislation, the entities working with medical devices must get an authorization which confirms the right to import / distribute / do warehousing/do servicing / do optic activities.	https://www.linkedin.com/in/raluca-megles-3534187/
Slovakia	slovak			
Slovenia	slovenian			
Spain	spanish	ongoing	In Spain we are waiting for the modification of the transpositions of the MDD and IVDD directives. Also here we have a local requirement of a safety officer "Tecnico Responsable" and is not clear if will be substituted by the PRRC We will provide information when published	https://www.linkedin.com/in/xaviercanalsriera/
Sweden	swedish			
Switzerland	german, french, italian	Post-Swexit https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/marktzugang.html		
UK	english	Post-Brexit https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk		