LANDSCAPE REVIEW OF IMPLEMENTING AND DELEGATED ACTS APPLICABLE TO EUROPEAN *MEDICAL DEVICE REGULATION 745/2017*

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Introduced by the Lisbon Treaty, IMPLEMENTING and DELEGATED ACTS are a new source of European law

European Commission

IMPLEMENTING ACTS

- IMPLEMENTING REGULATION
- IMPLEMENTING DECISION

Disciplined respectively by Articles 290 and 291 of the TFEU, they aim to improve the effectiveness of the European decision-making process by <u>simplifying</u> the implementation/execution procedure

This study investigated the Implementing and Delegates Acts pertinent to EU Medical Devices Regulation 745/2017 (MDR).

The aim of this work is to provide medical devices operators with an overview of the European measures enacted or still awaiting implementation.

DELEGATED ACTS

DELEGATED ACTS ART. 115 REGULATION (EU) 2017/745		
1	Art. 1 § 5	Amendment of the list of Annex XVI Reg. 2017/745 (non-medical products)
2	Art. 3	Edit definition of nanomaterial and related (particle, agglomerate, aggregate)
3	Art. 10 § 4	Amendment of Annexes II (technical documentation) and III (post marketing surveillance) of interest to manufacturers
4	Art 18 § 3	Edit list: suture materials, staples, dental filling materials, orthodontic appliances, dental crowns, screws, wedges, plates and prostheses, wires.
5	Art. 19 § 4	Modification of the content of the declaration of conformity (Annex IV Reg. 2017/745.)
6	Art. 27 § 10	Information modification annex VI (point B Data in the UDI database) and annex VI (point C choice of 2D / Matrix or RFID vector)
7	Art. 44 § 11	Monitoring and reassessment of notified bodies
8	Art. 52 § 5	Adding or removing the list of class IIb implantable devices (conformity assessment)
9	Art. 56 § 6	Modification of certificates of conformity (Annex XII) issued by the NBs.
10	Art. 61 § 8	Modification of the list of class IIb implantable devices for the purposes of patient health and safety. (evaluation and clinical investigation)
11	Art. 70 § 8	Amendments to the documentation to submit the clinical investigation application in the light of technical progress and international developments
12	Art. 106 § 15	Change of tasks expert groups and specialized laboratories

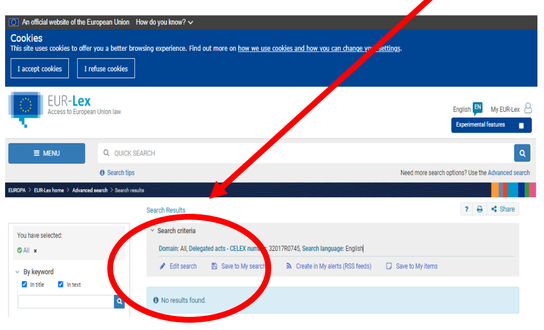
Elaborated by E. Rocchi

The result is an updated overview of a complex ongoing regulatory process. While eight Implementing Acts pursuant to Artt. 35, 27.2, 106.17, 10.6, 33.8, 5.6, 10.6, of MDR have been introduced by the Commission at different times, none of the twelve Delegated Acts referred to in Article 115 of Regulation has yet been forthcoming.

The not simple research conducted within the Eur-Lex database allowed its extrapolation, the consequent careful analysis and subsequent insertion, in the best possible summary, in in the table below:

IMPLEMENTING ACTS REGULATION (EU) 2017/745					
1	N° 2017/2185	IMPLEMENTING REGULATION	23/11/2017	Related list of codes and related types of devices intended to specify the purpose of the designation (the reason for the choice) of notified bodies in the medical devices sector pursuant to Regulation (EU) 2017/745 of the European and of the Council and of devices in vitro diagnostics in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council	25/11/2017
	Annex containing the codes of the different types of medical devices (and in vitro diagnostic) that can be used to select the notified bodies by the Authorities responsible for the notified bodies (art.35 Reg. 2017/745).				
2	N° 2019/939	IMPLEMENTING DECISION	6/06/2019	Designating the issuing bodies in charge of managing a unique device identifier (UDI) attribution system in the medical device sector	27/06/2019
	4 Issuing Agency: GS1 AISBL (per l'Italia) Health Industry Business Communications Council (HIBCC), ICCBB, Informationsstelle für Arzneispezialitäten – IFA GmbH rilasciano i codici UDI (Unique Device Identifier) (art. 27.2 Reg. 2017/745)				
3	N° 2019/1396	IMPLEMENTING DECISION	10/09/2019	Establishing detailed rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert groups in the field of medical devices	2/10/2019
	Indicazioni per autocandidatura in gruppi di esperti, in base al settore medico di competenza. (art.106 Reg. 2017/745)				
4	N° 2020/1207	IMPLEMENTING REGULATION	19/08/2020	Establishing detailed rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the common specifications for the reprocessing of single-use devices	26/05/2021
	'Refurbishment': a process performed on a used device to enable its safe reuse. (Reg. 2017/745 art. 2, 39) The reconditioner of the medical device is considered as the manufacturer (art.17 Reg. 2017/745), who is responsible for the reconditioning pursuant to art. 3 directive 85/374 / EEC				
5	N° 2021/1182	IMPLEMENTING DECISION	16/07/2021	Concerning the harmonized standards for medical devices drawn up in support of Regulation (EU) 2017/745 of the European Parliament and of the Council	20/07/2021
	5 Harmonized Standards (EN-ISO) hereby made mandatory (Article 10 §6 Reg. 2017/745)				
6	N° 2021/2078	IMPLEMENTING REGULATION	26/11/2021	Establishing rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council with regard to the European database of medical devices (Eudamed)	19/12/2021
	Eudamed: definitions, methods of access, registration and access, confidential website, operation, / malfunction, IT security, fraudulent activity (Article 33 § 8 Reg. 2017/745)				
7	N° 2021/2226	IMPLEMENTING REGULATION	14/12/2021	Establishing methods of application of Regulation (EU) 2017/745 of the European Parliament and of the Council with regard to electronic instructions for the use of medical devices	4/01/2022
	Instructions for the use of devices in electronic form (website or software for professional users) (Article 5 §6 Reg. 2017/745)				
8	N° 2022/6	IMPLEMENTING DECISION	4/01/2022	Amends Implementing Decision (EU) 2021/1182 as regards harmonized standards for the biological assessment of medical devices, sterilization of medical devices and health care products, aseptic treatment of health care products, the quality management systems, the symbols to be used in the information to be provided by the manufacturer, the packaging of health care products and phototherapy devices for home use	5/01/2022
	9 Harmonized rules here made mandatory for integration to Reg. 2021/1182 (Article 10 §6 Reg. 2017/745)				

Elaborated by E. Rocchi

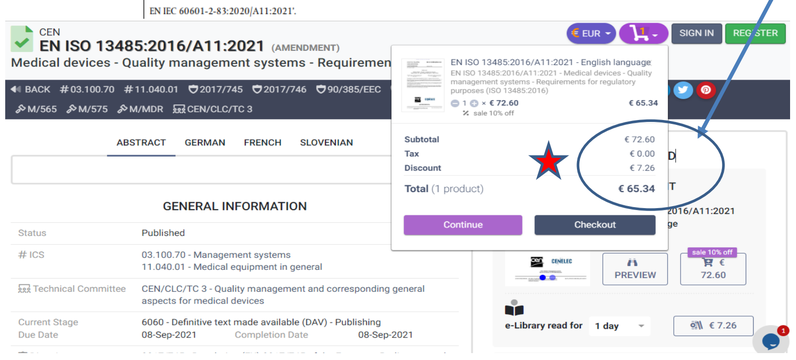


Unlike Implementing Acts, Implementing Decisions n. 2021/1182 and 2022/6 stand out for their clarity, with the specific ISO regulation on medical devices official acknowledged as a binding requirement.

ISO standard made COMPULSORY
by express reference in the Regulation 745/2017

No.	Reference of the standard
6.	EN ISO 10993-9:2021 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)
7.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
8.	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) EN ISO 11737-1:2018/A1:2021
9.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)
10.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/A11:2021
11.	EN ISO 14160:2021 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2020)
12.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
13.	EN ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)
14.	EN IEC 60601-2-83:2020 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment EN IEC 60601-2-83:2020/A11:2021'.

price



How the European Commission adopts IMPLEMENTING ACTS

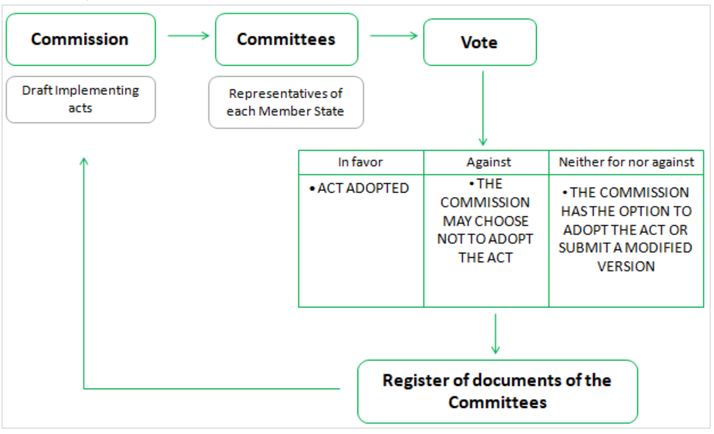
IMPLEMENTING REGULATION

PUBLIC CONSULTATION

The term "*comitology*" refers to a set of procedures that allow EU countries, through specific committees, to control the way in which the European Commission adopts implementing acts.

STAKEHOLDERS | **COMITOLOGY**

Stakeholders categories (non - exhaustive list)	
Internal	• Menagers • Manifacturing • Marketing • Legal • Distributors • Pharmaceutical industry • regulatory specialists
External	• Pharmacists • Regulators • Suppliers • Providers • users (doctors and nurses) • Society (Customers, Patients, Patients families, Clients) • Suppliers • wider community



IMPLEMENTING DECISION

AUTOMATICALLY ACTIVE

CONCLUSIONS

Although Implementing and Delegated acts have been established to simplify and speed up the decision-making process of the European Legislator, the 2017/745 Regulation is still in an evolutionary phase since it remains lacking in compliance in many of its parts as only Implementing acts have been carried out.

Bibliography and sitography
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing -Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)
https://eur-lex.europa.eu/legal-content/IT/TXT/URI?=CELEX%celex%3A32017R0745#:~:text=Regolamento%20(UE)%202017%2F745,rilevante%20ai%20fini%20del%20SEE.%20)
- C. Rivadossi, *Il TFUE e le nuove fonti del diritto dell'Unione Europea. Atti delegati e Atti di esecuzione a confronto*, 12 ottobre 2014, Cattedra di diritto pubblico, Università di Brescia.
https://www.forumcostituzionale.it/wordpress/wp-content/uploads/2013/05/rivadossi.pdf (d.u.c. 10/01/2022)
- J. Mendes, *Delegated and Implementing Rule Making: Proceduralisation and Consultation Design*,European Law Journal, Vol. 19, No. 1, January 2013, pp. 22–41
- European Standardization https://www.cencenelec.eu/european-standardization/ (d.u.c. 16/10/2021)
- https://ec.europa.eu/info/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts_it (d.u.c. 9/02/2022)
- Comitology
https://ec.europa.eu/info/law/law-making-process/adopting-eu-law-7implementing-and-delagatedacts/comitology_it
(d.u.c. 15/01/2022)
- Treaty on the Functioning of the European Union (consolidated version)
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:it:PDF (d.u.c. 05/02/2022)

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53. LANDSCAPE REVIEW OF IMPLEMENTING AND DELEGATED ACTS APPLICABLE TO EUROPEAN MEDICAL DEVICE REGULATION 745/2017

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- Consolidated version of the Treaty on the Functioning of the European Union https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:it:PDF - C. Rivadossi, Il TFUE e le nuove fonti del diritto dell'Unione Europea. Atti delegati e Atti di esecuzione a confronto, 12 ottobre 2014, Cattedra di diritto pubblico, Università di Brescia. https://www.forumcostituzionale.it/wordpress/wp-content/uploads/2013/05/rivadossi.pdf
- J. Mendes, Delegated and Implementing Rule Making: Proceduralisation and Consultation Design,European Law Journal, Vol. 19, No. 1, January 2013, pp. 22–41
- European Commission, questions and answers European nomenclature of medical devices https://ec.europa.eu/health/system/files/2021-10/md_q-a_emdn_it_0.pdfo
- European Standardization https://www.cencenelec.eu/european-standardization/
- https://ec.europa.eu/info/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts_it
- Comitology https://ec.europa.eu/info/law/law-making-process/adopting-eu-law/implementing-and-delegatedacts/comitology_it
- https://eurlex.europa.eu/search.html?SUBDOM_INIT=ALL_ALL&DTS_SUBDOM=ALL_ALL&DTS_DOM=ALL&lang=en&type=advanced&DB_IMPLEMENTING=32017R0745&qid=1636408561747
- https://eurlex.europa.eu/search.html?SUBDOM_INIT=ALL_ALL&DTS_SUBDOM=ALL_ALL&DTS_DOM=ALL&DB_DELEGATED=32017R0745&lang=en&type=advanced&qid=1636408628734rire testo