IMPLEMENTATION ROLLING PLAN
Regulation (EU) 2017/745 and Regulation (EU) 2017/746

This rolling plan contains a list of identified essential implementing acts and other relevant initiatives that the Commission has adopted or intends to adopt in the future. This plan is divided into two sections: implementing acts, and other actions/initiatives. This document is subject to quarterly review in order to provide national authorities and stakeholders with the most updated information.

This document shall be read in conjunction with the "MDR/IVDR roadmap" adopted by the Competent Authorities for Medical Devices (CAMD) in cooperation with the Commission (available at https://www.camd-europe.eu/regulatory/medical-devices-regulation-vitro-diagnostics-regulation-mdr-ivdr-roadmap). A list of ongoing MDCG guidance documents is available at https://ec.europa.eu/docsroom/documents/37921.

NOTE: Regulation (EU) 2020/561 of the European Parliament and of the Council deferred by one year the date of application of Regulation (EU) 2017/745, until 26 May 2021.

Latest update: December 2020

No.	Subject	Legal basis	Description	Expected timelines (expected date of final adoption/date of accomplishment)	State-of-play/Next step
			IMPLEMENTING ACTS		
1	Notified bodies scope of designation	Article 42(13) MDR Article 38(13) IVDR	Commission Implementing Regulation (EU) 2017/2185 Definition of the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. This action is an essential pre-condition for the launch of the designation procedure for Notified Bodies	24 November 2017	Published on 24 November 2017 COMPLETED
2	Reprocessing of single-use devices	Article 17(5) MDR	Commission Implementing Regulation (EU) 2020/1207 Common specifications laying down requirements related to reprocessing of single-use devices concerning risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing; the validation of procedures for the entire process, including cleaning steps; the product release and performance testing; the quality management system; the reporting of incidents involving devices that have been reprocessed; and the traceability of reprocessed devices.	Q3 2020	Published on 20 August 2020 COMPLETED

No.	Subject	Legal basis	Description	Expected timelines (expected date of final adoption/date of accomplishment)	State-of-play/Next step
3	Common specifications for products without a medical purpose	Articles 1(2) and 9(1) MDR	Commission implementing act Common specifications (CS) addressing for any of the groups of products listed in Annex XVI of the MDR, at least, application of risk management as set out in Annex I and, where necessary, clinical evaluation regarding safety. Application of MDR to Annex XVI products depends on the adoption of CS.	Q2 2021	In progress.
4	Setting up of expert panels	recital 94 Article 106(1) MDR	Commission Implementing Decision (EU) 2019/1396 Making provision for expert panels to be designated. Based on this implementing act, the selection of experts will be carried out. Expert panels are tasked inter alia with the delivery of opinions on the clinical evaluation of certain high-risk devices in the context of the pre-market scrutiny. Tasks of expert panels are described in Article 106(10).	Q3 2019	Published on 10 September 2019. COMPLETED
5	Setting up of expert laboratories	Article 106(7) MDR	Commission implementing act Designation of expert laboratories. Tasks of expert laboratories are described in Article 106(7). It shall be noted that the designation of expert laboratories is not mandatory.	-	Not in planning.
6	Setting up of new structures under IVDR: - EU reference laboratories	recital 94 Articles 48(6), 100(1) and (3) IVDR, Article 113(d) IVDR	Implementing Act (no comitology involved) Designation of EU reference laboratories, active in the IVD field. Tasks are described in Article 100. Designation may take place no earlier than 25 November 2020, according to IVDR Article 113(d).	Q3-4 2021	In preparation
7	Rules to facilitate fulfilment of tasks by EU reference laboratories and to ensure their compliance with criteria	Article 100(8)(a)	Implementing Act Rules to facilitate application of IVDR Article 100 (2) listing the tasks of the EURLs; rules to ensure compliance with criteria for an EURL listed in IVDR Article 100 (4). Date of application of the act may not be earlier than 25 November 2020 according to IVDR Article 113(d).	Q1 2021	In progress
9	Fees for EURL services	Article 100(8)(b) IVDR	Implementing Act Definition of rules for fees for the advice/testing activities performed by EURL. Date of application of the act may not be earlier than 25 November 2020 according to IVDR Article 113(d).	Q1 2021	In progress
10	Unique Device Identification (UDI) System: designation of issuing entities	Article 27(2) MDR Article 24(2) IVDR	Commission Implementing Decision (EU) 2019/939 Designation of one or more entities to operate a system for assignment of UDIs ('issuing entity').	6 June 2019	Published on 6 June 2019. COMPLETED

No.	Subject	Legal basis	Description	Expected timelines (expected date of final adoption/date of accomplishment)	State-of-play/Next step
11	EUDAMED	Article 33(8) MDR Article 30(1) IVDR	Commission implementing act Definition of detailed arrangements necessary for the setting up and maintenance of Eudamed. This IA is mainly related to support, change management and maintenance rules	Q1 2021	In progress
12	Common specifications for IVD Class D	Article 9 and 48(6) IVDR	Commission implementing act Common Specifications for certain IVDs in class D. Important to facilitate conformity assessment by manufacturers, notified bodies, expert panels and EU reference laboratories	Q2 2021	In progress
			ACTIONS/INITIATIVES (OTHER THAN IMPLEMENTING REGULATIONS/ACTS)		
1	Notified Bodies designation		Designation of Notified Bodies under the MDR and IVDR. Designation of Notified Bodies under the Regulations is a pre-condition for carrying out conformity assessments under those Regulations. List of notified bodies under MDR/IVDR available at: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main	Notified bodies are designated on a roling basis.	See New Approach Notified and Designated Organisations (NANDO).
5	EUDAMED go-live	Article 34 MDR	Eudamed may go-live from the moment a notice is published in the Official Journal of the European Union after a positive independent audit was performed that satisfies the MDCG	Notice to be published in 2022.	Deployment of fully functional EUDAMED intended to take place in 2022. In agreement with the MDCG, the Commission has pledged to make available the six modules on a roling basis as soon as each module becomes operational.

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3	EUDAMED: drawing up of functional specifications	Article 34(1) MDR	Functional specifications for Eudamed, to be drawn up by the Commission, in cooperation with the MDCG.	Q1 2019 (high-level functional specifications)	High-level functional specifications publically issued on the Commission website in March 2019.
4	EUDAMED: Audit of functional specifications	Article 34(2) MDR	Independent audit report based on which the Commission shall inform the MDCG that Eudamed has achieved full functionality and meets the drawn up functional specifications.	Should be finalised in 2022.	Pending.

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6	EUDAMED: Setting of helpdesk	MDR Art 33(8)	Detailed arrangements necessary for the setting up and maintenance of Eudamed means at least the setting of an helpdesk/application support for Eudamed (good IT practice and obligation under the implementing act).	Before Eudamed go-live	Available for Actor registration - UDI Helpdesk Q1 2021
7	Communication campaign		In order to avoid bottle necks and to ensure access to medical devices, a communication campaign targeting all stakeholders impacted by the Regulations is foreseen at least for 3 years. Targeted factsheets are produced for each target and the webpages of DG GROW on medical devices will be updated to provide more accurate and updated information.	Updated information to be provided during the transitional period of the Regulations. Examples of deliverables are information factsheets, targeted presentations, dedicated website.	The website dedicated to the Medical Devices Regulations is live. It has been transferred to SANTE webpages and it is continuously being updated. Social media campaign and targeted press release currently ongoing. Notifications are sent to subscribers of the Newsletter when new documents are published on the website.
8	Expert advisory structure: Setting of MDCG	Article 103 MDR	Establishing the Medical Devices Coordination Group (MDCG). The Group is composed of designated experts from Member States and chaired by the Commission. The Group provides advice and guidance on all matters related to the implementation of the Regulations.	26 November 2017 (Legal deadline)	Established by the legal deadline COMPLETED
9	Expert advisory structure: Setting of MDCG subgroups	Article 103 MDR	Setting of MDCG sub-groups, providing MDCG with the necessary expertise in relation to specific fields.	Establishment of MDCG Subgroup started in March 2019	Multiple MDCG Subgroups for different areas of the Regulations operational since March 2019. Latest Subgroup (on EUDAMED) established in April 2020. COMPLETED
10	Mandate to SCHEER on phthalates	Annex I Section 10.4.3 MDR	Mandate to the scientific Committee (SCHEER) to prepare guidelines on phthalates. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_015.pdf	18 June 2019	Adopted on 18 June 2019. COMPLETED
11	EU medical device nomenclature	Article 26 MDR and 23 IVDR	Designation of the future EU medical device nomenclature to be used in the UDI database	March 2019	Decision published on the Commission website in March 2019. COMPLETED
12	Standardisation Request	Article 10 of Regulation (EU) No 1025/2012 (the 'Standardisation Regulation') and Articles 8(1) of the MDR and IVDR	MDR/IVDR Standardisation Request by the Commission to the relevant European standardisation organisations (CEN and CENELEC) for development of harmonised European standards in the field of medical devices in support of the requirements of the new Regulations. The existing standards harmonised under the current Directives need to be revised to align them to the new legislative framework, and new standards need to be developed	Q1 2021	After the rejection by CEN/CENELEC of the act adopted by the Commission in June 2020, a new draft of the Commission Implementing Decision for the MDR/IVDR Standardisation Request is under development, to be submitted to the opinion of the Committee on Standards, then to be adopted by the Commission and addressed to CEN/CENELEC for their acceptance.