

MDR / IVDR - IMPLEMENTATION ROLLING PLAN

This Rolling Plan contains the list of identified essential implementing acts and actions to be put in place by the Commission during the transitional period together with relevant information on expected timelines and state-of-play. The information is organised into two main sections (implementing acts and other actions/initiatives). The document will be subject to quarterly review in order to provide the authorities and stakeholders with the most updated information. This document shall be read in conjunction with the “MDR/IVDR roadmap”, produced by the Competent Authorities for Medical Devices project (CAMD) in cooperation with the Commission (and available at <https://www.camd-europe.eu/regulatory/medical-devices-regulation-vitro-diagnostics-regulation-mdr-ivdr-roadmap>), which contains a much more comprehensive overview of all the initiatives (including guidance) expected to be undertaken during the transitional period by the Commission and the National Competent Authorities

Latest update: February 2019

No.	Subject	Legal basis	Description	Expected timelines (expected date of final adoption/date of accomplishment)	State-of-play/Next step
IMPLEMENTING REGULATIONS/ACTS					
1	Notified bodies scope of designation	Article 42(13) MDR Article 38(13) IVDR	Implementing Act 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	26 November 2017 (Legal deadline)	Adopted and published on 24 November 2017 COMPLETED
2	Reprocessing of single-use medical devices	Article 17(5) MDR	Implementing Act 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.	November 2019 It shall be noted that, in the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions	Formal public consultation (Q2 2019)
3	Common specifications for products without a medical purpose	Articles 1(2) and 9(1) MDR	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.	Q1 2020	Informal consultation with stakeholders on a draft text to be launched by Q1 2019
4	Setting up of expert panels	recital 94 Article 106(1) MDR	Implementing Act (no comitology involved) 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	Draft implementing act in preparation

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5	Setting up of expert laboratories	Article 106(7) MDR	Implementing Act (no comitology involved) 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.	TBD (not before 2020)	Survey with MDCG members and stakeholders finalised. While the issue of expert laboratories is under investigation, the appointment of expert laboratories does not constitute a priority
6	Setting up of new structures under IVDR: - EU reference laboratories	recital 94 Articles 48(6), 100(1) and (3) IVDR	Implementing Act (no comitology involved) Designation of EU reference laboratories, active in the IVD field. Tasks are described in Article 100	Q4 2019/Q1 2020	Survey with MDCG members and stakeholders finalised. This is intended to support the drafting of the future act.
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)	Q4 2019/Q1 2020	Survey with MDCG members and stakeholders finalised. This is intended to support the drafting of the future act.
8	Fees for expert panel services	Article 106(13) MDR	Implementing Act Definition of fees for the advice provided by expert panels	Q4 2019	Survey with MDCG members and stakeholders finalised. This is intended to support the drafting of the future act.
9	Fees for EURL services	Article 100(8)(b) IVDR	Implementing Act Definition of fees for the advice/testing activities performed by EURL	Q2 2020	Survey with MDCG members and stakeholders finalised. This is intended to support the drafting of the future act.
10	Unique Device Identification (UDI) System: designation of issuing entities	recital 94 Article 27(2) MDR recital 94 Article 24(2) IVDR	Implementing Act (no comitology involved) Designation of one or more entities to operate a system for assignment of UDIs ('issuing entity').	Q2 2019	Call for application for UDI issuing entities expired on 25 January. Evaluation of applications ongoing.

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11	EUDAMED	Article 33(8) MDR Article 30(1) IVDR	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	Q4 2019	Drafting to start by Q1 2019
12	Common specifications for IVD Class D	Article 9 and 48(6) IVDR	Implementing Act/s Common Specifications for IVD Class D in the context of the scrutiny mechanism for high risk devices	Q4 2019	As soon as the last Common Technical Specifications are adopted under the current Directive 98/79/EC (adoption expected Q1 2019), the new Common Specifications under the Regulation will be drafted
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 of conformity assessments under the new Regulations	As many Notified Bodies as possible designated prior to May 2020	42 applications received by the Commission services, 25 joint assessments carried out and 3 more already scheduled. Full scope of MDR and IVDR covered in the applications.
2	EUDAMED: Implementation plan	Article 34(1) MDR	Plan for the implementation of the functional specifications for Eudamed to be drafted by the Commission.	Legal deadline for first release: 26 May 2018.	COMPLETED First release done in due time (25 May). Work in progress for further releases

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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	Version 3 of high-level functional specifications were issued end of October 2018. Version 4 finalised and presented at the MDCG meeting of February 2019. It is estimated that modules for clinical investigation and market surveillance might be only partly or not at all available at the time of application of the two Regulations (due to workability issues) but few months after.
4	EUDAMED: Audit of functional specifications	Article 34(2) MDR	Independent audit report based on which the Commission shall inform the MDCG when it has verified that Eudamed has achieved full functionality and meets the drawn up functional specifications	Audit to start in Q3/Q4 2019. Must be finalised by Q1 2020.	First analysis of type of contract done. Contract content to be determined starting from Q1 2019 (first draft of technical annex ongoing)
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 by 25 March 2020	Work in progress to elaborate functional specifications and implement them
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 (normal IT good practice and implementing act obligation).	Before Eudamed go-live (March 2020)	Internal preparatory work has started.
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 new dedicated website and first updated library are live. New factsheets have been published in January 2019. Release of existing factsheets in some major non-EU languages has also started. Social media campaign under preparation.
8	Expert advisory structure: Setting of MDCG	Article 103 MDR	Setting of MDCG as an expert group of the European Commission. MDCG, composed by MS experts and chaired by the Commission, provides advice on all matters related to the implementation of the Regulation.	26 November 2017 (Legal deadline)	Established by the legal deadline COMPLETED

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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.	To be completed by Q1 2019	Assessment of submitted applications from stakeholders associations ongoing. Formal establishment of the MDCG subgroups expected Q1 2019.
10	Mandate to SCHEER on phthalates	Annex I Section 10.4.3 MDR	Mandate to the scientific Committee (SCHEER) to prepare guidelines on phthalates	26 May 2018 (Legal deadline)	COMPLETED in September 2017. SCHEER's opinion expected in mid-2019
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	Decision is expected by Q1 2019	On the basis of the report of the EU task-force on nomenclature and the indications provided by the MDCG at its meeting of 30 November, the Commission is currently finalising its assessment in the view of a final decision to be taken by Q1 2019

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12	Standardisation mandate	Article 10 of Regulation (EU) No 1025/2012 (the 'Standardisation Regulation')	Request to the European Standardisation Organisations for development of standards in the field of medical devices - the existing standards harmonised under Medical Device Directives need to be aligned to the new framework.	Decision is expected by Q2 2019	<p>The consultation of MS and Cen/Cenelec on the scope of the mandate (number of standards) was completed. The consultation of MS and Cen/Cenelec on the draft mandate (conditions for development of standards) is to be launched by Q1 2019.</p>