

IMPLEMENTATION OF THE NEW EU MEDICAL DEVICE REGULATIONS MDR (2017/745) AND IVDR (2017/746)

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1 Introduction

The EU's Medical Device Regulation (EU 2017/745) and In Vitro Diagnostic Regulation (EU 2017/746) – MDR and IVDR, respectively – have entered into force on 26 May 2017. They shall be applied after the graduated transitional periods, ranging from six months to five years, have ended for different stakeholders; thereby setting the general application date to spring 2020 for the MDR and spring 2022 for the IVDR. The transition timelines are illustrated in this [overview](#) issued by the European Commission.

Guidance documents are necessary to support the implementation of the forthcoming medtech Regulations, as these make provisions for implementing and delegated acts. Common specifications are required and the functioning of the medical device database, Eudamed, is a prerequisite for the full employment of the new regulatory framework.

ISS Integrated Scientific Services has been entrusted by the Federal Office of Public Health FOPH (Bundesamt für Gesundheit BAG) to report on the ongoing developments related to these Regulations as well as their implementation and further elaboration. Subsequent reports will be published at three-month intervals. The thematic focus of the reports will be on the research, in particular clinical trials; related aspects of the Regulations and their implementation; and the relevant modules in Eudamed.

2 Abbreviations

CS	Common Specifications
EC	European Commission
EMA	European Medicines Agency
IVDD	In Vitro Diagnostics Directive 98/79/EC
IVDR	In Vitro Diagnostics Regulation (EU) 2017/746
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation (EU) 2017/745
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
UDI	Unique Device Identifier

3 Consolidated MDR & IVDR versions available

Consolidated versions of the IVDR/MDR legal texts are now available:

- [IVD Regulation](#)
- [Medical Devices Regulation](#)

4 Implementing and delegated acts & guidelines

The rolling plan for [MDR and IVDR implementing measures](#) lists essential implementing acts, actions and guidance to be put in place by the Commission and/or the MDCG. It is subject to quarterly review to provide updated information on the implementation process. The latest version was updated in August 2019. In addition to the updates outlined in the following chapter, this document announces updates such as:

- (3) Common Specifications on MDR Annex XVI, i.e., products without an intended medical purpose. Discussions with Member States took place in May and June 2019. This Implementing Act is now undergoing formal adoption.
- (6) EU Reference labs: The call for nominations is under preparation.
- (7) Rules to facilitate fulfilment of tasks by EU reference laboratories: The corresponding Implementing Act is in preparation.
- (9) Fees for EU reference laboratories services: The corresponding Implementing Act is in preparation.

4.1 MDCG document on obligations of notified bodies released

The Medical Device Coordination Group has released a Q&A document ([MDCG 2019-6](#)) aimed at notified bodies answering questions that have been identified in the process of joint assessments. The document clarifies new obligations under the MDR/IVDR and emphasizes that NBs cannot accept any application under the regulations before their designation becomes valid on the day after the notification in the EC's database NANDO.

4.2 Draft standardisation request

The EC has issued a [request](#) to the European standardisation authorities (the European Committee for Standardisation CEN and the European Committee for Electrotechnical Standardisation CENELEC) to draft revisions to existing standards and create new standards in line with the EU's medical device and in vitro diagnostic regulations (MDR/IVDR). The request lists 57 existing standards in need of revision and six to be drafted in support of the MDR; and 39 existing standards in need of revision and three to be drafted in support of the IVDR. The deadline for the adoption by the European standards organizations for the majority of the MDR and IVDR standards is 27 May 2024.

4.3 Implementing decision on UDI-issuing entities

The [implementing decision 2019/939](#) reveals that GS1, the Health Industry Business Communications Council (HIBCC), ICCBA, and Informationsstelle für Arzneispezialitäten (IFA GmbH) will be issuing entities for unique device identifiers (UDIs). The designations are valid for five years.

4.4 Proposed common specifications for the reprocessing of single-use medical devices

In July 2019, the EC proposed the common specifications (CS) for the reprocessing of single-use medical devices under the MDR via a [draft implementing regulation](#) in alignment with Article 17(3). EU member states may choose not to apply the outlined rules concerning the reprocessing and reutilization of single-use devices within health institutions, provided the safety and performance profile of the reprocessed device is equivalent to that of the original device and that the reprocessing is performed in accordance with the CS. Member states may also elect to apply such rules for an external reprocessor to reprocess single-use devices at the request of a health institution subject to both criteria from Article 17(3).

4.5 Guidance on Article 15 regarding a person responsible for regulatory compliance (PRRC)

In July 2019, the MDCG ([MDCG 2019-7](#)) released a guidance document on Article 15 of the MDR regarding the person responsible for regulatory compliance (PRRC). Companies are required to have at least one employee responsible for regulatory compliance within their organisation. The guidance clarifies the requirements concerning the necessary qualifications of this person and the meaning of 'within their organisation' and 'permanently and continuously at their disposal' if the PRRC is not an employee of the organisation (which is possible for micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC).

4.6 MDCG guidance on implant cards

In July 2019, the MDCG issued a guidance ([MDCG 2019-8](#)) explaining the specifics of the implant card required by Article 18 of the MDR. The document describes the intended use, content and information to be provided by the manufacturer on the implant card, as well as the national implementations Member States have to put in place.

4.7 MDCG guidance for manufacturers of Class I medical devices

The Medical Device Coordination Group (MDCG) has drafted a guidance document that describes how manufacturers of Class I medical devices (other than custom-made devices) who place medical devices on the market under their name or trade mark meet the provisions of the MDR. A preliminary version of the text was circulated for comments, the document is not yet publicly available.

4.8 Draft documents on equivalence and sufficient clinical data circulating for comment

The European Commission has circulated draft guidelines on 'equivalence' and 'clinical evidence needed for medical devices previously certified under Directives 93/42/EC and 90/385/EC (legacy medical devices)' for comment. The document is not yet publicly available.

Recognizing that some of the recommendations set out in the current version of the European clinical evaluation guideline MEDDEV 2.7/1 rev. 4 do not comply with the relevant MDR requirements, the Commission recommends further guidance. Accordingly, the EC has prepared a draft guideline on equivalence to highlight the differences between MEDDEV 2.7/1 rev. 4 and MDR. A further aim of this document is to provide additional explanations for the determination and proof of equivalence with an existing medical device based on the MDR requirements for clinical evaluation.

In addition, the EC has asked competent authorities and observer stakeholders for feedback on a draft guideline on 'Clinical evidence needed for medical devices previously certified under Directives 93/42/EC and 90/385/EC (legacy medical devices)'. This guideline is intended to assist manufacturers and notified bodies in preparing for the conformity assessment of medical devices which are currently still certified according to the Directives. This guideline is to be used during the period of validity of existing certificates issued to the requirements of the AIMD, MDD and IVDD Directives as described in Article 120(2) and (3) of the MDR.

4.9 EC calls for observers for the nomenclature sub-group of the MDCG

A working group will be established to assist and advise the MDCG on implementation issues related to medical device nomenclature, especially concerning the update and maintenance of the EU nomenclature, as well as on ways to use it in contexts other than UDI registration (such as market surveillance). The [call](#) for observers was published in July; submission deadline was 5 August 2019.

4.10 EC previews calls for expert panels

In a published [information sheet](#), the EC informed that a call for applications to set up expert panels for premarket product evaluation consultation procedures provided under the EU's medical device regulation (MDR) will be issued later in 2019.

4.11 EC communication campaign includes two new factsheets

The EC issued a [factsheet](#) for healthcare professionals and health institutions acknowledging that the MDR could have an impact on the availability of medical devices and lead to a situation where some devices are temporarily unavailable. The factsheet includes a checklist for preparedness for healthcare institutions.

A new [factsheet](#) on UDI was published in August: Unique Device Identification (UDI) System – FAQs.

4.12 Additional guidance to MDD vigilance system published

[Additional guidance](#) in relation to the vigilance system currently in operation under the MDD (to complement the MEDDEV 2.12-1 rev 8 from 2013) was published in July 2019. It refers to the new manufacturer incident report form (MIR) that will become mandatory from January 2020 and introduces the use of adverse event terminology of the IMDRF, the use of UDI, and a single registration number (SRN) in preparation for the MDR.

4.13 EMA issues draft guideline on quality requirements for drug-device combinations

The EMA issued a [draft guideline](#) dealing with the implementation of the Medical Devices Regulation, in particular Article 117. The document defines which quality-relevant information drug-makers must submit about the medical device components of their products in the context of initial marketing authorisation and during the product life cycle.

5 Eudamed

The EC enables economic operators to test the [Eudamed](#) interface in relation to the modules 'registration of operators' and 'UDI'. Only persons registered as manufacturers in Eudamed can register a UDI.

5.1 Guidance documents on data exchange in Eudamed published

Eudamed data exchange guidelines were published towards the end of May 2019 to support decision-making among competent authorities, notified bodies and economic operators on data exchange solutions for compliance with MDR's future version of Eudamed. The Eudamed data exchange [guideline](#) introduces three input methods:

- user interface (will be the simplest option in terms of data handling and manipulation)
- XML (is expected to be useful when Eudamed goes live to upload data in bulk using XML)
- machine-to-machine system (should only be considered under a specific set of conditions, outlined in the respective documents data exchange)

The [document](#) on data exchange services and entity models introductions addresses M2M data exchanges and a [guideline](#) provides M2M data exchange services definitions.

5.2 Draft Eudamed reporting templates circulating for comments

MDR Article 80 states that any 'serious adverse event' must be reported by the sponsor of a clinical trial. According to MDR Article 73, this report must be made via the Eudamed database. The working group Eudamed Clinical Investigation CI/PS developed a draft of a Eudamed reporting template, 'Serious Adverse Events (SAE)'. The Commission has circulated this draft for consultation. The document is not yet publicly available.

6 Notified body designation

The August [revision](#) of the rolling plan, as well as the July [update](#) of the state of play of joint assessment, shows progress in the NB designation process, with four NBs currently designated under the MDR, 52 applications reviewed, 33 joint assessments, and seven more assessments scheduled.

NANDO currently lists four NB designated under the MDR (BSI UK, TÜV SÜD, DEKRA, IMQ).

The following NBs have withdrawn their services under the current MDD/IVDD:

- Lloyd's Register Quality Assurance (LRQA) (also withdrew MDR/IVDR designation application)
- UL UK ceases operations under the MDD and limits its work under the IVDD
- QS Zürich (also withdrew MDR designation application)
- ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH (currently no intention to pursue MDR designation)

The announced withdrawal from the NB services of London-based Lloyd's Register Quality Assurance (LRQA) may impact the IVDR transition, as LRQA was handling a large share of the IVD certification under the IVDD.

7 Implementation activities on national levels

7.1 France – ANSM announced clinical investigation pilot under MDR

In July 2019, France's ANSM [announced](#) the launch of a pilot on clinical investigations under the MDR in autumn this year. The MDR introduces changes that result in new workflows relating to clinical investigations

among EU competent authorities and ethics committees. The pilot will start mid-September and will allow for the simulation of the new working method in line with MDR provisions, i.e. the deadlines for the assessment of files and the coordination. ANSM hopes that the pilot will make the EU more attractive for the industry to conduct research, foster innovation, and enhance the transparency around and access to data from clinical investigations.

The pilot applies to Class III implantable, Class IIa or Class IIb invasive devices, including those without CE marks and products without a medical purpose, across all therapeutic areas.

7.2 UK – MHRA revised guidance on clinical investigations in line with MDR

The MHRA revised the medical device clinical investigation [guidance](#) to reflect changes introduced by the MDR. The guidance points to the legislative provisions relating to biological safety evaluation under Annex XV of the MDR. The revision introduces the need for ensuring that the ‘anticipated benefits to the patients enrolled in the clinical trial justify the foreseeable risks’, in accordance with Article 62 of MDR, and for submitting sufficient data for review to ‘provide assurance that all necessary toxicological risks have been appropriately considered’. Other updates apply to toxicological risk assessments and conformity assessment requirements.

7.3 UK – Updated guidance on substantial amendments to a clinical trial in a no-deal scenario

The MHRA has updated the [guidance](#) by removing some outdated background information and re-wording some content to focus on the actions clinical trial sponsors will need to take.

7.4 UK – Two notified bodies will continue their UK medtech business

Two notified bodies announced their intention to continue their UK medtech business whatever the Brexit outcome: BSI and SGS. This will be vital information for anyone wanting to market their products in the UK after Brexit.

8 IVD-specific issues

The first IVDR corrigenda specified that rules on performance studies should be in line with well-established guidance documents, such as ISO 20916. The newest version of [ISO 20916](#) *In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice* was published in May 2019 and part of the draft standardisation request the EC sent to the European standardisation authorities.

9 Sources

ANSM: [Medical Device Clinical Investigations submitted to the ANSM and Ethics Committee within the pilot phase](#) (July 2019).

European Medicines Agency: [Draft Guideline on the quality requirements for drug-device combinations](#) (29.05.2019)

European Commission: [Transition Timeline from the Directives to the Regulations](#) (12.04.2019).

European Commission: [Commission Implementing Decision \(EU\) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers \(UDIs\) in the field of medical devices \(Text with EEA relevance.\)](#) (06.06.2019).

European Commission: [M2M Data Exchange Services Definitions](#) (29.05.2019).

European Commission: [Eudamed Data exchange services and entity models introductions](#) (29.05.2019).

European Commission: [Eudamed Data Exchange Guidelines](#) (29.05.2019).

European Commission: [Factsheet for healthcare professionals and health institutions](#) (17.06.2019).

European Commission: [European Commission expert panels on medical devices and in vitro diagnostic devices](#) (21.06.2019).

European Commission: [Draft standardisation request as regards medical devices in support of Regulation \(EU\) 2017/745 and in vitro diagnostic medical devices in support of Regulation \(EU\) 2017/746](#) (26.06.2019).

European Commission: [state-of-play of joint assessments of Notified Bodies in the medical device sector](#) (01.07.2019).

European Commission: [Call for applications: observers for the nomenclature sub-group of the medical device coordination group](#) (05.07.2019).

European Commission: [Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8](#) (10.07.2019).

European Commission: [Draft Implementing Act issued: Single-use medical devices - safety and performance requirements for reprocessing](#) (23.07.2019).

European Commission: [Unique Device Identification \(UDI\) System – FAQs](#) (12.08.2019).

European Commission: [MDR and IVDR implementing measures rolling plan](#) (12.08.2019).

European Commission, Medical Device Coordination Group: [MDCG 2019-6 Questions and answers: Requirements relating to notified bodies](#) (06.06.2019).

European Commission, Medical Device Coordination Group: MDCG 2019-8 [Medical Devices: Guidance document Implant Card relating to the application of Article 18 Regulation \(EU\) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices](#) (01.07.2019).

European Commission, Medical Device Coordination Group: [MDCG 2019-7 Guidance on Article 15 of the Medical Device Regulation \(MDR\) and in vitro Diagnostic Device Regulation \(IVDR\) regarding a "person responsible for regulatory compliance" \(PRRC\)](#) (01.07.2019).

ISO: [SO 20916:2019 In Vitro Diagnostic Medical Devices - Clinical Performance Studies using specimens from human subjects - Good Study Practice](#)

MHRA: [Clinical investigations of medical devices – biological safety assessment](#) (July 2019).

MHRA: [Guidance on substantial amendments to a clinical trial if the UK leaves the EU with no deal](#) (last updated 07.08.2019).