INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

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

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Content

1 Introduction

The EU's Medical Device Regulation (EU 2017/745) and In Vitro Diagnostic Regulation (EU 2017/746) – referred to as MDR and IVDR, respectively – have entered into force on 26 May 2017. Both regulations are applicable to a wide range of stakeholders once the graduated transition periods, ranging from six months to five years have come to pass.

Guidance documents are necessary to support the application of the forthcoming MedTech Regulations, as these make provisions for implementing and delegated acts. In addition, the establishment of common specifications and a functional medical device database, EUDAMED, are prerequisite for the comprehensive 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 provide comprehensive updates 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, with a thematic focus on research, particularly in the realm of clinical trials. These reports will also delve into pertinent aspects of the Regulations and their implementation, alongside an exploration of the relevant modules in EUDAMED.

2 Abbreviations

DSVG	Device Specific Vigilance Guidance
EC	European Commission
EMA	European Medicines Agency
EMDN	European Medical Device Nomenclature
IoT	Internet of Things
IVDD	In Vitro Diagnostics Medical Devices 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
UDI	Unique Device Identification

3 Proposal to amend MDR and IVDR to gradually roll-out EUDAMED issued

In January 2023, the European Commission proposed new measures to improve the implementation of MDR and IVDR. This followed a hard-fought battle by industry and other stakeholders:

- A further extension of the transition periods for most devices under the IVDR;
- Earlier mandatory implementation of most parts of the EUDAMED medical device database;
- A requirement for manufacturers to give prior notice before interrupting the supply of critical medical devices and IVDs.
- The Commission will start preparatory work for a targeted evaluation of the application of the Regulations in 2024 (in accordance with Article 121 MDR and Article 111 IVDR).

In its proposal, the Commission aims to ensure that the modules of EUDAMED, the EU's medical device database, will be phased in on a mandatory basis as soon as they are declared operational, rather than waiting for the full set of six modules to be ready for a single launch. Three modules are already available for voluntary use to register actors, UDI/devices, and notified bodies and their certificates. Mandatory use of these five modules could start in late 2025, while work continues on the clinical investigations and performance studies module, which will be launched later. Once each module is up and running, stakeholders will only have to register once with EUDAMED, and national registrations will cease. In addition to the proposal, the European Commission has published answers to the most frequently asked questions about the regulation of IVDs and the phased implementation of EUDAMED.

The Commission's 26-page proposal has been submitted to the European Parliament and the Council of the EU for adoption. The EU Council agreed on its mandate on 14 February 2024, without seeking amendments.

This is not the first time that the original deadlines for most IVDs have been extended. The Commission had already responded to concerns that IVDs would not meet the original implementation deadlines. It issued an amending regulation, which entered into force on 25 January 2022, extending the transition periods to 26 May 2027.

4 Implementing Delegated Acts & Guidelines

4.1 MDCG updates guidance on importer and distributor requirements

The MDCG has published an updated Q&A document on how the new medical device and in vitro diagnostic regulations affect importers and distributors to further clarify their requirements.

4.2 Revised MDCG guidance on PRRC provides additional information

The MDCG has updated its guidance regarding the individual responsible for regulatory compliance under the MDR and the IVDR. The update clarifies the role and responsibilities of the individual, including Eudamed registration and the handling of custom-made devices. MDCG also states that the person in this role should not suffer any consequences for diligently performing their duties.

4.3 MDCG guidance issued on permissible use of equivalence in clinical investigations

In December 2023, the MDCG published a new guidance to clarify the exemptions from the requirement to conduct clinical investigations and related conditions for demonstrating equivalence for implantable and Class III devices. The document provides examples and considerations relevant to demonstrating sufficient access

to the data according to Annex XIV, Section 3 of the MDR. Appendix I of the guidance document contains flowcharts to illustrate cases where implantable and Class III devices may be exempted from mandatory clinical investigations. Appendix II of the guidance document contains tables showing the hierarchy of levels of access to data regarding the clinical, technical and biological characteristics to be considered for the demonstration of equivalence.

4.4 MDCG issued updated Q&A document regarding clinical investigations

The MDCG has published a revised version of its Q&A document on clinical investigations. Several new questions have been added, and some answers have been modified to provide further clarification on the requirements for clinical investigation.

4.5 MDCG guidance documents on classification and equivalence for non-medical devices published

The MDCG has published two new guidance documents relating to Annex XVI products. The first guidance document, MDCG 2023-5, is a 14-page guide for manufacturers and notified bodies on the qualification and classification of Annex XVI products. The second, MDCG 2023-6, is a four-page guide for manufacturers and notified bodies on how to demonstrate equivalence for Annex XVI products.

4.6 Commission designates five EU reference laboratories for high-risk IVDs

The European Commission has recently appointed five EU reference laboratories for high-risk IVDs. These laboratories will be responsible for performing certain tasks, such as verifying the performance of Class D devices, assessing compliance with common specifications, and conducting batch testing. The designation of these laboratories is required by the IVDR, and they will start supporting conformity assessments from 1 October 2024. These designated laboratories cover four categories of Class D IVDs, namely hepatitis and retroviruses, herpesviruses, bacterial agents and respiratory viruses that cause life-threatening diseases.

4.7 Manufacturer vigilance templates issued for CE-marked devices

The European Commission has published a number of documents to assist manufacturers with post-market surveillance and vigilance reporting. The MDCG 2024-1, Device Specific Vigilance Guidance (DSVG) template provides the format for device categories specific guidelines. This will allow standardisation of the way incidents for different devices are reported to the EU Competent Authorities under the requirements of the MDR and IVDR.

Three of the first four device categories relate to cardiology, a high-risk area. The fourth product category relates to breast implants, which is a topic of controversy due to safety concerns. Each document contains a table indicating what should be reported as individual serious incidents and what should be included in periodic summary reports and what should be reported if a trend is identified. These are accompanied by codes established by the International Medical Device Regulators Forum that apply to each type of issue

- MDCG 2024-1-1 Guidance on the vigilance system for CE-marked devices - DSVG 01 Devices for Cardiac Ablation
- MDCG 2024-1-2 Guidance on the vigilance system for CE-marked devices - DSVG 02 Coronary Stents and associated delivery systems
- MDCG 2024-1-3 Guidance on the vigilance system for CE-marked devices - DSVG 03 Cardiac Implantable Electronic Devices (CIEDs)
  MDCG 2024-1-4 Guidance on the vigilance system for CE-marked devices DSVG 04 Breast Implants

4.8 MDCG guidelines outline procedure for EMDN updates

In February 2024, the MDCG issued guidelines outlining the procedures for updating the European Medical Device Nomenclature (EMDN). MDCG 2024-2 details the annual revision process and a pilot procedure for expedited ad-hoc updates. The European Commission has set up an online platform to receive proposals for

updating of the EMDN. Following evaluation of the proposals, a new version will be published at the end of each calendar year as described in MDCG 2024-2.

5 Notified body designation

5.1 43 notified bodies designated under the MDR, 12 under the IVDR

By the end of February 2024, there were 43 notified bodies designated under the MDR, while 12 were designated under the IVDR.

The following additional NBs with MDR designations are listed in NANDO:

– Institute For Testing And Certification (ITC), Czech Republic

6 Implementation activities on national levels

6.1 Belgium: New Royal Decree amends national requirements for medical devices and IVDs

On 7 December 2023, a Royal Decree was published in the Belgian Official Journal amending various Decrees relating to clinical investigations and performance evaluations.

6.2 Denmark: DMA issues guidance on coordinated application process for combined studies

The updated regulations of Clinical Trials Regulation (CTR) and the In Vitro Diagnostic Regulation (IVDR) may create difficulties for clinical trials simultaneously investigate an in vitro diagnostic device (IVD). In such cases, the sponsors must obtain authorization for both the clinical trial of the medicinal product and the performance study of the IVD before initiating the clinical trial. The Danish Medicines Agency has issued guidance on how sponsors of combined studies can now apply through a nationally coordinated process.

6.3 Norway: Norwegian Medicines Agency becomes Norwegian Medical Products Agency

Since 1 January 2024, the Norwegian Medicines Agency is now known as the Norwegian Medical Products Agency (NOMA). The newly renamed agency has increased responsibilities in emergency preparedness and public financing of medical products compared to its previous portfolio.

7 Miscellaneous

7.1 European Commission publishes dashboard with data on adoption of MDR, IVDR

The European Commission has recently published a dashboard containing data gathered from assessments of the availability of medical devices and IVDs under the MDR and IVDR. The dashboard presents the results of a three-year study on the availability of medical devices, together with data collected from previous studies conducted by notified bodies. The dashboard currently focuses on notified body data. However, it will gradually be expanded to include reports from various stakeholders, including manufacturers and authorized representatives, health service providers, patient representatives, and competent authorities.

7.2 European Commission publishes overview of national language requirements

The European Commission has published the overview tables for the MDR and IVDR, which list the language requirements for manufacturers at the national level concerning the information accompanying the medical device.

7.3 EC considers second call for EU reference laboratories for high-risk IVDs

The European Commission has consulted with the Member States in the Medical Device Coordination Group and is now considering launching a second call to cover the remaining categories of Class D devices. These categories include arboviruses, haemorrhagic fever and other biosafety level 4 viruses, parasites, and blood grouping. Interested laboratories are invited to inform their Member State of their interest by April 30, 2024. If there is significant interest, a formal call for applications may be launched soon.

7.4 Team NB publishes position paper on medical device lifetime

Team NB has issued a position paper to promote consistency in the approach to device lifetime, as there is no specific definition for it within the MDR and IVDR. This paper provides an overview of existing guidance and standards, identifies expectations, and illustrates the issue matter for different types of devices.

7.5 MedTech Europe proposals to streamline EU medical device reporting requirements

As part of the European Commission's Public Consultation on the rationalisation of EU reporting requirements, MedTech Europe has highlighted areas where reporting requirements in EU legislation for medical devices can be simplified, minimised or digitalised for medical technologies. MedTech Europe has identified 20 reporting areas across the MDR, the IVDR, the Artificial Intelligence Act, the Animal By-Products Regulation, and the Corporate Sustainability Act where administrative burdens could be reduced.

7.6 EMA issues guidance on the use companion diagnostics in drug development

The European Medicines Agency (EMA) has addressed frequently asked questions about the use of companion diagnostics in drug development. The guidance document is based on the implementation of the IVDR.

7.7 New EU Data Act establishing data access and use rules comes into force

The EU Data Act, which stipulates harmonised rules for fair access to and use of data, came into effect on 11 January 2024, and it will become applicable in September 2025. The Data Act will enable a fair distribution of data value by establishing transparent and fair rules for accessing and using data within the European data economy. It covers any Internet of Things (IoT) device or wearable that collects data about the user or their environment, including medical and health devices. It applies to most digital health stakeholders, such as software manufacturers, medical device companies, and suppliers of related services, who want to sell their products or services in the European Union market.

8 Sources

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European Commission: Data Act (27.02.2024).

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