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) – MDR and IVDR, respectively – have entered into force on 26 May 2017. Both regulations are applicable for various stakeholders once the graduated transition periods, ranging from six months to five years have come to an end.

Guidance documents are necessary to support the application of the forthcoming MedTech Regulations, as these make provisions for implementing and delegated acts. Common specifications, and a functional medical device database, EUDAMED, are 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 research, in particular clinical trials; related aspects of the Regulations and their implementation; and the relevant modules in EUDAMED.

2 Abbreviations

AEMPS	Spanish Agency for Medicines and Health Products
AIMDD	Directive 90/385/EEC
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte, Germany
EC	European Commission
FAMHP	Federal Agency for Medicines and Health Products, Belgium
FIMEA	Finnish Medicines Agency
HPRA	Health Products Regulatory Authority, Ireland
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
MPDG	Medizinprodukterecht-Durchführungsgesetz, Germany
MPG	Medizinproduktegesetz, Germany
NANDO	New Approach Notified and Designated Organisations
QMS	Quality Management System
UDI	Unique Device Identification

3 MDR and IVDR amending regulation (EU) 2023/607 in force

The Medical Device Regulation in the European Union underwent a long-awaited amendment, which was adopted and published on 20 March 2023. It came into effect on the day of its publication in the Official Journal of the European Union. The European Commission (EC) expedited these changes to avoid device shortages throughout the EU, caused by the MDR. As a result, legacy products that meet certain conditions can avoid the previous deadline of May 26, 2024, which required an MDR conformity assessment certificate from a notified body.

Regulation (EU) 2023/607 changes the transition deadlines as follows:

Date	Deadlines
20 March 2023	Entry into force of the EU 2023/607 amending regulation
26 May 2024	Deadline to lodge an application and to have an MDR QMS in place
26 September 2024	Deadline to sign a written agreement and transfer appropriate surveillance to an MDR notified body
26 May 2026	End of transitional period for class III custom-made implantable devices to be placed on the market without a certificate
31 December 2027	End of transitional period for class III or class IIb implantable devices (if not explicitly exempted)
31 December 2028	End of transitional period for other class IIb, IIa and I devices with a sterile or measuring function that have a notified body involvement

Surrounding this new arrangements around legacy products, an additional Q&A document was swiftly published, which aims to assist stakeholders understand how the new ruling should be applied.

4 Implementing and delegated acts & guidelines

4.1 New delegated regulations change schedule for reassessing NBs under MDR and IVDR

The EC recently released two delegated regulations, that alter the schedule for reassessing notified bodies under the MDR and IVDR. Before these changes were implemented, notified bodies were required to undergo reassessment three years after their initial notification, and subsequently every four years. However, to allocate more time for existing MDR/IVDR notified bodies and concentrate resources on new assessments, the Commission has reset the reassessment interval to five years. This new timeline is now in effect, although some notified bodies may still be assessed more frequently than this five year interval.

4.2 Updated UDI helpdesk online

In May 2021, the EC established a Helpdesk to aid in the implementation of the Unique Device Identification (UDI) system requirements. The UDI Helpdesk was later enhanced, and since 14 March 2023, a new version with additional information and FAQs was made accessible.

4.3 EC issues guidance on content and structure of summary of clinical investigation report

In May 2023, the EC released a guidance on the content and structure of the summary of the clinical investigation report in the context of the MDR.

4.4 Confirmation letter template to demonstrate compliance with new MDR transition deadlines available

In early May, Team NB issued a letter template which notified bodies can use to demonstrate that their clients may continue to market eligible legacy devices until the new transition deadlines. The EC further published this letter template on its website on 23 May 2023.

4.5 MDCG guidance on significant changes updated to align with MDR amendment

The MDCG has recently revised its guidance document on significant changes which are applicable to legacy devices. These changes are connected to Article 120 of the MDR and align with the amending regulation's extended transitional provisions.

4.6 EC issues proposal to align transition deadlines of Annex XVI products

The EC is proposing to align the deadlines of Annex XVI products with the amended regulation's extended transitional provisions. For Annex XVI products that do not require clinical investigation, the transition period would end on 31 December 2028. However, products which require a clinical investigation, these legacy devices must comply with the MDR and the common specifications by 31 December 2029. Additional conditions must be fulfilled to make use of the extended deadlines.

5 EUDAMED

5.1 New EUDAMED information centre available

The EU provides a new EUDAMED information centre, which includes action steps and process logic from a wide range of documentation. This information centres also includes a detailed FAQ section and a library of all user guides.

5.1 MedTech Europe asks Member States to keep EUDAMED voluntary

MedTech Europe called on the Member States to keep the use of EUDAMED voluntary until it is fully operational. MedTech Europe, therefore, asks the Member States to uphold the national processes. Nevertheless, MedTech Europe agrees that EUDAMED can be a voluntary alternative to complying with national registration requirements instead of being the only way to comply with registration requirements.

6 Notified body designation

6.1 38 notified bodies designated under the MDR, ten under the IVDR

By the end of May 2023, there were 38 notified bodies designated under the MDR, while ten were designated under the IVDR.

The following additional NB with MDR designation is listed in NANDO:

– SZUTEST Konformitätsbewertungsstelle, Germany

7 Implementation activities on national levels

7.1 Belgium: Actors must submit turnout declaration for medical devices distributed in Belgium

In 2023, the FAMHP in Belgium will implement a new financing system for monitoring medical devices. The goal of this system is to distribute fees fairly among all stakeholders in the sector. Previously, only those distributing to retailers and end-users were responsible for paying the fees.

7.2 Denmark: Information for manufacturers of Annex XVI published

Similar to medical device manufacturers, manufacturers of products without an intended medical purpose must register with, and pay a fee to the Danish Medicines Agency. Starting from 22 June 2023, companies that make, import, or distribute these products will also need to inform the Danish Medicines Agency, if they have any connections with healthcare professionals or offer financial support to professionals. This is in accordance with section 5B(5) of the Danish Act on Medical Devices.

7.3 Finland: Fimea launches medical device advisory clinic to answer question concerning clinical trials

The Medical Devices Unit of Fimea recently launched the Medical Device Advisory Clinic in April. This clinic is available to support and assist researchers during the planning stage of their study, especially when they are still trying to come to terms with the official requirements.

7.4 Finland: Fimea announces new electronic service for certain medical device actors

Fimea will open a new electronic transaction service at the end of spring 2023. The new service will make it easier to report operator and device information to the national register while ensuring that your information remains current. These transactions are not intended for operators which are subject to EUDAMED's notification.

7.5 Germany: BfArM updates document overview for clinical trial application

The BfArM updated the overview of documents including their designation in the DMIDS that must be submitted for either clinical trials, performance studies or performance evaluation according to MDR/IVDR and MPDG or MPG.

7.6 Germany: Third revision of Medizinprodukte-Abgabeverordnung is in force

With the third amendment, Annex 3 to Section 3 (4) of the Medizinprodukte-Abgabeverordnung has been expanded to include in-vitro diagnostics for self-testing, for the detection of influenza viruses.

7.7 Germany: BfArM updates information site on reporting

In March 2023, the BfArM updated the relevant information on incident reporting and SAE (serious adverse events) as well as DD (device deficiencies) in clinical trials.

7.8 Ireland: HPRA issues application form for clinical investigations of non-CE-marked devices

The HPRA issued a new version of its application form for clinical investigations with non-CE-marked medical devices in Ireland.

7.9 Italy: National process to apply Article 59 of MDR outlined in recent circular

The Italian Ministry of Health issued a circular to outline the national process to apply Article 59 in light of the amended transition timelines of the MDR.

7.10 Italy: New breast implant register established

A new regulation for establishing a national register for breast implants was published in the Official Gazette on 18 January 2023 and entered into force on 2 February 2023. Even the economic operators who distribute

these devices in Italy must transmit data relating to every breast prosthesis marketed and intended to be implanted, both for aesthetic and reconstructive purposes. The national register of breast implants will be fed with data from regional registers.

7.11 Italy: New decree on ethic committees' involvement in clinical trials with medical devices

In February 2023, four decrees were published to significantly improve the regulatory approval process for clinical trials in Italy by streamlining the role of the ethic committees.

7.12 Italy: New decrees implement advertising rules for medical devices and IVDs

The Ministry of Health published two decrees to implement advertising regulations for medical devices and in vitro diagnostic medical devices.

7.13 Spain: Updated information on clinical trial requirements

The Spanish Agency for Medicines and Health Products (AEMPS) renewed the authorization request procedure for clinical investigations using medical devices. New instructions are available on AEMPS' website to clarify the different types of clinical investigations with these products, the requirements applicable to each of them, and other national requirements.

7.14 Spain: New Royal Decree introduces national provisions for medical devices

In March 2023, Royal Decree 192/2023, outlining how the country's medtech regulations may diverge from requirements in other EU countries, was published. The Royal Decree deals with provisions that are the remit of the EU Member States, such as reprocessing and in-house manufacture.

7.15 Spain: Procedure for requesting the application of Article 59 of the MDR

The AEMPS outlined the procedure to apply Article 59 of the MDR in case of certification gaps.

7.16 Turkey: New guideline outlines recall procedure for medical devices

The Turkish Authorities issued the *Guideline on Withdrawal and Recall of Medical Devices and In Vitro Diagnostic Devices from the Market,* which applies within the scope of Law No. 223 on *Product Safety and Technical Regulations*. The guidance determines the procedures implemented to prevent unsafe and inappropriate medical devices from being placed on the market and the responsibilities of the relevant parties in this context.

7.17 Turkey: Communiqué to outline rules on electronic IFU issued

In July 2022, the Turkish Medicines and Medical Devices Agency has issued a communiqué on instructions-for-use in electronic form, in accordance with Commission Implementing Regulation (EU) 2021/2226.

8 Miscellaneous

8.1 Team NB survey results show progress towards MDR & IVDR certification

A survey conducted by Team NB gathered information from its 33 members to assess the current state of the industry and the progress of the transitions to MDR and IVDR. The survey revealed a significant increase in submissions for certification under MDR in 2022, with the number of applications almost doubling to 9,615 when compared to the previous year.

8.2 Team NB issues second version of MDR technical documentation submission best practices

Team NB has updated its guidance on submitting technical documentation for the MDR. This update expands on the reasons for delays in the review process, highlighting incomplete or inconsistent device descriptions as

a common issue. The new version (Version 2) also references MDCG guidance's and provides more detailed explanations of its impact. Team NB published the original guidance in October 2022.

8.3 Team NB issues position paper on best practice for the submission of technical documentation under IVDR

Team NB published a document outlining the best practices for the submission of certain technical documents under the IVDR.

8.4 Team NB updates position paper on hybrid audits

Team NB has revised and reissued the position paper related to the use of hybrid audits in the assessment of quality management systems under the MDR/IVDR.

8.5 MedTech Europe issues third version of IVDR clinical evidence requirements guidance

MedTech Europe published its guidance on clinical evidence requirements applicable under the IVDR.

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