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

AIMDD	Directive 90/385/EEC
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte, Germany
BMBF	The Federal Ministry of Education and Research, Germany
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and Health Care
EMA	European Medicines Agency
DMIDS	Medical Device Information and Database System, Germany
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 European Commission Survey Results: MDR and IVDR certificates and applications

According to the latest figures from a European Commission survey, notified bodies operating under EU's Medical Device Regulation (MDR) have granted nearly 4,000 conformity assessment certificates. These mark a significant increase of 32% from the number of certificates granted at the end of March 2023. The numbers have been published as part of a three-year study to monitor the availability of medical devices on the EU market. The study commenced almost a year ago and will continue until 1 December 2025. The survey, conducted in July 2023 collected data from all 39 notified bodies designated at the time until 30 June 2023, compared to previous survey data. Manufacturers submitted a total of 13,177 applications for MDR device conformity assessment by the end of June 2023, reflecting a 22% increase from three months earlier. The document also provides a table detailing reasons for application refusal by notified bodies, for the three latest periods, emphasising issues such as incomplete applications and insufficient understanding of their different remits. The survey also highlighted a noteworthy increase in IVDR certificates, reaching 500 by June 2023 – a more than 50% rise from March 2023 figures. Additionally, the number of IVDR applications has risen by 22%. As of June 2023, out of the 1,155 submissions, 231 were for the highest risk IVDs, which fall under class D. Furthermore, 62 out of the 500 certificates issued were for class D devices.

With an additional survey, the European Commission is consulting to assess the information requirements of companies affected by the MDR & IVDR. The Commission seeks feedback on the relevance an informativeness of the documents, gauging their potential for being shared with other stakeholders through social media and websites. Furthermore, additional questions are being asked on the clarity of the language used in the communications. If there are any issues with clarity, the specific problem needs to be identified. Additionally, the survey seeks to determine the extent to which the materials meet the needs of stakeholders affected by the regulations.

Another EC survey aimed at manufacturers and authorised representatives, targets to understand and improve the monitoring of medical devices availability on the EU market.

The European Commission (DG SANTE) and the European Health and Digital Executive Agency (HaDEA) have commissioned the consulting firm EY to conduct the study; *Study on Regulatory Governance and Innovation in the field of Medical Devices,* on the development of the regulatory environment following the introduction of the MDR and IVDR. The outcome will then lead to the publication of a final report by the end of 2024, including recommendations for the future of the MDR/IVDR and their governance structure.

A member of the European Parliament, Sirpa Pietikäinen, has submitted a written parliamentary question to the European Commission regarding the equal access to medical innovations for European patients. In response, Ms Kyriakides, on behalf of the Commission, has outlined measures to ensure that medical devices are available and accessible to patients.

4 Implementing Delegated Acts & Guidelines

4.1 EC issues Q&A on the transitional provisions for products without an intended medical purpose

The European Commission issued a Q&A document regarding the application of the transitional provisions of the MDR to products without an intended medical purpose.

4.2 New MDCG guidance on MDSW hardware combinations

MDGG 2023-04 clarifies regulatory requirements on medical device software (MDSW) intended to work with hardware or hardware components. It examines which specific regulatory considerations apply when the hardware or hardware component incorporating the data collection element is a medical device or an accessory to a medical device.

4.3 Delegated Regulation on assignment of UDI for contact lenses published

The European Commission has released a delegated regulation on the assignment of unique device identifiers (UDIs) to contact lenses. The regulation sets the application date to 9 November 2025.

4.4 MDCG updates position paper to urge manufacturers to have products certified

The MDCG has recently released a revised position paper, urging manufacturers to utilise the extended timelines for the MDR and IVDR Certification to avoid potential market removal. Although many manufacturers have applied to certify their products under the MDR and IVDR since the deadline extensions, not enough are taking advantage of the new timelines.

4.5 The Commission's implementing regulation identifies the first designated IVDR reference labs

The first batch of reference laboratories, that will play a crucial role in the future evaluation of high-risk IVDs have been designated. The commission implementing regulation (EU) 2023/2713 contains the details of these laboratories. However, these labs are not expected to start activities until 1 October 2024.

4.6 Version 3 of borderline manual issued

The MDCG Borderline and Classification Working Group released a new version of the manual on borderline and classification under MDR and IVDR. The latest entries cover endovascular adhesives, sensors, irrigation solutions, custom-made implants and more.

5 EUDAMED

5.1 Updated EUDAMED draft timeline indicates another delay

The European Commission's official site now features a new draft timeline for the finalisation of EUDAMED, citing 2027 as the official launch date. Notably, the clinical investigations and performance studies modules, poses the critical challenges, with the other modules being ready and available much sooner.

The new timeline introduces two EUDAMED audits, with the first audit will beginning in Q2 of 2024 and concluding by the year's end.
The clinical investigation/performance studies (CI/PS) module will be developed from the 2nd quarter of 2024 until the 3rd quarter of 2026. An audit is scheduled for this module between the end of 2026 and the beginning of 2027. EUDAMED is expected to offer full functionality in the first quarter of 2027.

The use of EUDAMED for device and certificate registration will become mandatory by Q2 of 2029 (24 months after the full functionality). All other modules will be compulsory as of Q4 of 2027, six months after the full functionality.

6 Notified body designation

6.1 42 notified bodies designated under the MDR, 12 under the IVDR

By the end of November 2023, there were 42 notified bodies designated under the MDR, while 12 were designated under the IVDR.

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

- Scarlet NB, Netherlands
- Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi, Turkey
- UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş., Turkey

The following additional NBs with IVDR designations are listed in NANDO:
- Eurofins Electric & Electronics Finland Oy, Finland
- Sertio Oy, Finland

7 Implementation activities on national levels

7.1 Czech Republic: National medical device database to be replaced with new system

In the first quarter of 2024, the Medical Device Register RZPRO will be replaced entirely by the Medical Device Information System ISZP. The ISZP is intended to be a supplementary system at the national level, to EUDAMED. In the future, EUDAMED data will be used to fulfil reporting obligations for distributors, service providers, and manufacturers of custom-made medical devices within the ISZP system interface. Due to the delay in launching EUDAMED, reporting obligations in the ISZP will be provisionally adjusted so that they can be performed without data registered in EUDAMED

7.2 Finland: New regulation for professional users to notify dangerous situations

As of November 1, 2023, Regulation 1/2023 mandates new rules requiring professional users to report hazardous situations concerning medical devices. The regulation supplements Section 33 of the Finnish Medical Devices Act and aims to ensure comprehensive and uniform information content of emergency notifications.

7.3 Germany: Modernisation of the DMIDS module for clinical trials/performance studies

Sponsor must submit the relevant applications for clinical trials or performance studies online via the German Medical Device Information and Database System (DMIDS). The BfArM has now announced on its website that a routine for deleting drafts will be introduced on 1 January 2024 to modernise the DMIDS module for clinical trials/performance studies. Applications and notifications that have been inactive for more than six months will be deleted. Ongoing applications are not affected.

7.4 Germany: Guideline on categorisation of clinical trials with medical devices issued

The Federal Ministry of Education and Research (BMBF) has launched the national community portal MedTec Online. The free specialised portal serves to provide information, communication and cooperation within the MedTech community.

7.5 Ireland: New FSC application for legacy devices with extended transition period

The HPRA provides a new Certificate of Free Sale (FSC) application form for medical devices qualifying under Regulation (EU) 203/607. An FSC issued for these devices is valid for three years.

7.6 Italy: Updated registration process for custom-made devices

Since 25 September 2023, the online service for the registration of manufacturers who make custom-made medical devices available on the national territory is operational.

7.7 Italy: Update of national database to enter information on systems and procedure packs

Since 26 October 2023, an update to the national database in Italy allows for the entry of information regarding systems and procedure packs (as stated in Article 22 of the MDR), including details on changes introduced by Regulation (EU) 2023/607.

7.8 Netherlands: New investigational IVD device dossier template available

Since 15 September 2023, the Central Committee on Research Involving Human Subjects website has provided the Investigational In Vitro Diagnostic Medical Device Dossier (IMDD-IVD) template. This model is intended for IVD-performance studies that apply to Article 58 of the IVDR.

7.9 Slovak Republic: Notification required for first placement on market

The State Institute for Drug Control SUKL has confirmed that manufacturers, authorised representatives, importers and distributors of medical devices or IVDs who make these devices available on the Slovak market must notify the devices within 14 days. Unless specifically requested, this notification requirement does not apply to class I medical devices and class A IVDs.

8 Miscellaneous

8.1 Combine project analyses regulatory landscape for combined clinical trials

The European Commission has launched a call for participation in a stakeholder reference group to enable direct interaction with the EU Commission/MDCG/CTCG project on combined clinical trials.

8.2 New venture to offer matchmaking platform for market operators and notified bodies

The venture *Notified Body Increased Capacity (NoBoCap) is* being established to ensure that innovative health solutions can reach the EU market more quickly and efficiently. NoBoCap is an EU4Health 36-month-long project co-funded by the EU. It will offer long and short-term training courses on high-priority topics for new recruits and specialist workforce in notified bodies and market operators, coaching and internship sessions, and a matchmaking platform connecting market operators with the appropriate notified bodies.

8.3 Team NB calls IVD manufacturers to apply for certification

Team NB issued a press release to urge manufacturers of class D devices to seek certification under the IVDR this year, emphasizing the need for timely application processing. Team NB's concerns are based on the fact that the IVDR reviews for high-risk devices last from 13 to 18 months and the volume of submissions received to date.

8.4 EC expert panels advised MDCG on COVID-19 antibody test

EC expert panels have provided guidance to the MDCG regarding COVID-19 antibody tests. The MDCG sought advice on whether a serological test can accurately detect neutralizing anti-SARS-CoV-2 antibodies and, if not, what studies would be required to support such a claim. The experts emphasized distinguishing between binding and neutralizing antibodies in their response.

8.5 EDQM issues survey results on authorities' responses to falsified medical devices

The European Directorate for the Quality of Medicines and Health Care (EDQM) surveyed European Authorities to understand their perception of the medical device falsification and how they address this problem. The survey findings were published recently, revealing that the root of the problem lies in the lack of understanding of the nature of medical devices.

8.6 First dermal filler CE-marked under Annex XVI of the MDR

Austrian's Croma-Pharma received the first CE mark for a dermal filler under Annex XVI of the MDR.

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