INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

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

UPDATE FOR THE FEDERAL OFFICE OF PUBLIC HEALTH (BAG), FEBRUARY 2023

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

AIMDD	Directive 90/385/EEC
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte, Germany
CCMO	Centrale Commissie Mensgebonden Onderzoek, Netherlands
CECP	Clinical Evaluation Consultation Procedure
EC	European Commission
ECJ	European Court of Justice
EURLs	EU Reference Laboratories
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
NB	Notified Body
QMS	Quality Management System

3 European Parliament votes to extend MDR transition period

On 16 February 2023, the European Parliament agreed to the text of the "commission proposal for a Regulation" which will not only extend deadlines for legacy products under the MDR, but also remove the deadline for putting into service devices in the context of the IVD Regulation and the MDR.
The changes to MDR's Article 120, will introduce extended transition periods for legacy devices and therefore lengthen the period for which these devices can be placed on the market. The amended Article 120(3) alters the transition periods as follows:

– For class III and IIb implantable devices (with some exceptions), the transition deadline is extended until 31 December 2027.
– For the remaining class IIb devices, class IIa devices and class I devices (placed on the market in sterile condition or with a measuring function), the transition deadline is extended until 31 December 2028.

The extension is subject to conditions ensuring that only safe devices benefit from the additional time. Moreover, the manufacturers need to have taken certain steps to transition towards compliance with the MDR. The changes to Article 120(2) of the MDR keep (AI)MDD certificates valid (or allow them to be re-validated in the case of expired certificates). However, certain requirements need to be met for all devices, which include;

– that the device does not undergo significant changes until that date,
– the device remains compliant with Directive 90/385/EEC or Directive 93/42/EEC and
– the MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators are applied and replaces the corresponding requirements in those Directives.

New, is the condition that a device can only benefit from the extension as long as it does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Not to be underestimated is the requirement stipulating that a complete MDR QMS has to be implemented (Article 120 (3d)) until 26 May 2024, and a conformity assessment application has to be underway at a notified body, for which a written agreement is required before 26 May 2024. Furthermore, by the 26 September 2024, the notified body and manufacturer must have signed a written agreement regarding the conformity assessment. This follows the intention that only devices that manufacturers intend to transition to the MDR will benefit from the extended transition period.

The following conditions apply to re-validate certificates that were still valid on 26 May 2021 but will have expired before the amendment to the MDR enters into force require:

– either a written agreement between manufacturer and a notified body (issued before the date of expiry of the certificate) for the MDR conformity assessment, either for the device covered by the expired certificate or, for a device intended to substitute said device; or
– a derogation of the applicable conformity assessment procedure granted by a competent authority of a Member State according to Article 59(1) of the MDR, or a Member State has requested the manufacturer to carry out the applicable conformity assessment procedure to restore conformity, in accordance with Article 97(1) of the MDR.

The extension of the validity of certificates with this amending Regulation decreases the potential burden on competent authorities to resolve device shortages with Article 97.

4 Implementing and delegated acts & guidelines

4.1 Guidance on allowing legacy devices to remain on the market with expired MDD/AIMDD certificates

In MDCG 2022-18, the MDCG provides a common understanding and uniform approach to applying Article 97 of the MDR. Article 97 can be applied by competent authorities of Member States to allow devices which are not in conformity with the MDR to remain on the market. Their non-conformity with the MDR is due to the fact that certificates which have been issued under the Directives, having expired or will expire before the issuance of the necessary MDR certificates.

4.2 MDCG publishes guidance on periodic safety update reports

MDCG 2022-21 provides guidance on implementing the legal requirements for periodic safety update reports (PSUR) for class IIa, IIb, and II medical devices according to Article 86 of the MDR.

4.3 New MDCG Q&A provides details on vigilance terms and concepts of MDR

In a new Q&A document, the MDCG answers questions about vigilance terms and concepts used in the MDR. The document clarifies the difference between an incident and a serious incident and also provides a flowchart to support the evaluation of an incident.

4.4 MDCG issues new information on hybrid audits under MDR/IVDR

In a new position paper, the MDCG defines hybrid audits as requiring at least one auditor to be present on the premises, allowing other team members to participate remotely. Notified bodies must plan and document which parts of the audit activities are carried out on-site, and which will be carried out remotely.

4.5 MDCG revises guidance on appropriate surveillance of legacy devices

MDCG 2022-4 summarises the surveillance activities performed by notified bodies as defined in the MDR's transitional provisions (Article 120(3)). The first revision of this document includes amendments to align the guidance with newer MDCG publications, such as MDCG 2022-14 and MDCG 2022-15.

4.6 Updated MDCG document on requirements related to notified bodies issued

MDR Article 36(1) / IVDR Article 32(1) specifies requirements for notified bodies and their personnel. The personnel referred to in the respective regulations perform critical functions within the notified body and shall therefore be employed by the notified body itself. The fourth revision of MDCG 2019-6 clarifies the term "employed" in this context. It defines the minimum criteria for the compliant contractual relationship between the notified body and the individual.

4.7 MDCG issues templates for notified bodies to make standard fees public

According to Article 50 of the MDR, notified bodies must make their standard fees publicly available. MDCG 2023-2 provides templates for notified bodies to list standard fees applicable to conformity assessment activities under the MDR and IVDR.

4.8 MDCG provides templates for IVDR performance study procedures

MDCG 2022-19 and MDCG 2022-20 contain templates and other supporting documents for performance studies under the IVDR. Specific national provisions of the Member States may apply additionally, and the forms match the planned data fields in EUDAMED. Once the database module is available, the templates will be withdrawn.

4.9 MDCG guidance on rules applicable to in-house devices

Article 5(5) of the MDR and IVDR lays out the rules applicable to in-house devices, for which most other provisions do not apply. MDCG 2023-1 provides guidance for healthcare professionals and researchers who design, manufacture, modify and use in-house devices.

4.10 Updated guidance on IVD classification under IVDR

MDCG has updated its guidance on the rules for classifying IVDs, adding an annex explaining the process for determining if an IVD is a companion diagnostic.

4.11 Updated information pack for potential reference laboratories available

The European Commission has revised the information for candidate EU reference laboratories, including clarifications on performance studies sample sizes, financial viability checks and the independence and impartiality of reference laboratories.

4.12 Common specifications for devices without an intended medical purpose

Commission Implementing Regulation (EU) 2022/2346 specifies the common specifications for products without an intended medical purpose listed in Annex XVI of the MDR.

4.13 Re-classification rules of certain active products without intended medical purpose

Commission Implementing Regulation (EU) 2022/2347 re-classifies certain active products without an intended medical purpose listed in Annex XVI of the MDR. This was necessary since the classification rules 9 and 10 of Annex VIII cannot be applied, resulting in such products being classified as class I in accordance with rule 13.

4.14 Updated version of borderline manual and classification decisions available

In December 2022, the second version of the manual on borderline and classification for medical devices under the MDR and IVDR was published. The new entries are the outcomes of the decisions on medical calculators and needle counters.

4.15 EMA pilots project to provide scientific advice to manufacturers of high-risk medical devices

In February 2023, the EMA launched a pilot project to provide scientific advice as part of the expert panels established under the MDR to manufacturers of high-risk devices intended to administer or remove medicinal products from the body.

5 EUDAMED

5.1 Functional specifications for the version of EUDAMED to be audited published

The European Commission published the functional specifications for the European Database for Medical Devices (EUDAMED). This document will serve for the independent audit that will be carried out to verify that EUDAMED (only the "Minimum Viable Product", the legal priority) has achieved full functionality.

5.2 New EUDAMED production version available

The European Commission has made a new EUDAMED production (version 2.10) available with improvements to the modules "actors", "UDI/Device", and "NB & Certificates". The release notes on this new version are available in the EUDAMED help menu and information Centre. The data exchange service is active and the new version affects the XSD version number of the data exchange services. Therefore, stakeholders must adjust the version number in their service requests. This information should be communicated to the person(s) managing the access point they use (internal or third party).

6 Notified body designation

6.1 37 notified bodies designated under the MDR, ten under the IVDR

By the end of February 2023, there are 37 notified bodies designated under the MDR, while ten are designated under the IVDR.

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

- ICIM S.P.A., Italy
- SLG PRÜF UND ZERTIFIZIERUNGS GMBH, Germany

The following additional NBs with IVDR designation are listed in NANDO:

- QMD Services GmbH , Austria
- MDC MEDICAL DEVICE CERTIFICATION GMBH, Germany
- 3EC International, Slovakia

The EU Commission updated and published the summary on the coverage of designation codes for notified bodies designated under the MDR and the IVDR in January 2023. An overview of applications for designation as a notified body under the MDR and IVDR was presented during the MDCG meeting on 6 February 2023

7 Implementation activities on national levels

7.1 Czechia: Act on medical devices and IVDs in force

The Act on Medical Devices and In Vitro Diagnostics Medical Devices (Act No. 375/2022 Coll.) aligns the Czech legislation with the MDR and IVDR, outlining national provisions such as specific language requirements and the national database.

7.2 Denmark: Clarifications on notification requirements before starting clinical investigations or performance studies in Denmark

The Danish Medicines Agency updated its website to inform sponsors about the notification requirements before the start of the clinical investigation or performance studies and which application forms to use for authorisation.

7.3 Estonia: Revised medical device act extends national notification requirements

The revised Medical Device Act introduces changes to the national provisions applicable to medical devices, specifying requirements concerning the production, distribution and use of medical devices. In addition, the revision introduces extended notification requirements for distributors, specifically for systems, procedure packs, and class B, C and D IVDs placed on the market under the IVDR.

7.4 Germany: BfArM updates information for application on clinical trial/ performance study decision

BfArM updated its website to provide what information must be included, when requesting a decision on the classification and approval requirements of a clinical trial or performance study. The decisions are made case-by-case, and BfArM charges a fee for this service.

7.5 Netherlands: Clinical trial sponsors now obligated to explain patient involvement in research file

As of 1 March 2023, it will be mandatory for all medical device and drug clinical trial sponsors to explain how they involved patients at various stages of study design, execution and reporting, or offer a justification why and where, this was not the case.

7.6 Sweden: New vigilance reports submission process applicable

Since 1 December 2022, reports on serious incidents and events (MIR), field safety corrective actions (FSCA), periodic summary report (PSR), and trend reports, must be submitted to the Swedish Medicines Agency via an e-service. Reports for medical devices and IVDs must be submitted via this e-service until Eudamed is fully operational.

8 Miscellaneous

8.1 European Commission issues annual overview of clinical evaluation consultation procedure

On 16 January 2023, the European Commission published the document Annual overview of devices subject to the clinical evaluation consultation procedure (CECP).

8.2 European Court of Justice rules on medical device cases

The European Court of Justice (ECJ) has ruled in joint cases C-495/21 and C-496/21, on the distinction between medical devices and medicinal products, including pharmacological and non-pharmacological agents.

8.3 Team NB issues position paper in response to MDCG 2022-14

In a newly issued position paper, Team NB responds to item number 17 of the MDCG document 2022-14, which names the possibility for notified bodies to issue certificates under certain conditions. Team NB addresses the fact that there are no specific references to such conditions and that it will not consider issuing certificates under certain conditions as a routine mechanism.

9 Sources

BfArM: Antrag auf Entscheidung über die Genehmigungspflicht einer klinischen Prüfung eines Medizinprodukts oder einer Leistungsstudie eines In-vitro-Diagnostikums (retrieved 09.01.2023).
CCMO: From 1 March 2023 patient participation in the research file (05.01.2023).
Danish Medicines Agency: Performance studies of in vitro diagnostic medical devices (IVDs) (03.02.2023).
Danish Medicines Agency: Application for the authorisation for performance studies of in vitro diagnostic medical devices (03.02.2023).
Danish Medicines Agency: Clinical investigation of medical devices (03.02.2023).
Danish Medicines Agency: Application for clinical investigation of medical devices (03.02.2023).
EUDAMED: EUDAMED Release Note (23.02.2023).
EMA: Information session on the pilot for expert panels' scientific advice to manufacturers of high-risk medical devices (25.01.2023).
European Commission: Updated information pack for candidate EU reference laboratories published (30.11.2022).
European Commission: Functional specifications for the European Database on Medical Devices (EUDAMED) - to be audited (only for Minimum Viable Product (MVP) Legal Priority) (15.12.2022).
European Commission: Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices Version 2 (December 2022).
European Commission: Update - Coverage of designation codes by MDR/IVDR notified bodies - January 2023 (13.01.2023).
European Commission: Annual overview of devices subject to the clinical evaluation consultation procedure (CECP) - April 2021- June 2022 (23.01.2023).
European Commission: Overview of CAB/NBs at each stage of the designation process (07.02.2023).
European Commission, Medical Device Coordination Group: MDCG 2019-6 Rev4 Questions and answers: Requirements relating to notified bodies Revision 4 (October 2022).
European Commission, Medical Device Coordination Group: MDCG 2022-4 Rev.1 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (December 2022).
European Commission, Medical Device Coordination Group: MDCG 2022-17 - MDCG position paper on 'hybrid audits' - December 2022 (December 2022).
European Commission, Medical Device Coordination Group: MDCG 2022-19 Performance study application/notification documents under Regulation (EU) 2017/746 (MDCG, December 2022).
European Commission, Medical Device Coordination Group: MDCG 2022-20 - Substantial modification of performance study under Regulation (EU) 2017/746 (MDCG, 14.12.2022).
European Commission, Medical Device Coordination Group: MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 (MDCG, 16.12.2022).

European Commission, Medical Device Coordination Group: MDCG 2023-1 - Guidance on the health institution exception under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 - January 2023 (10.01.2023).
European Commission, Medical Device Coordination Group: MDCG 2023-2 List of standard fees (12.01.2023).
European Commission, Medical Device Coordination Group: Update - MDCG 2020-16 Rev.2 - Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 (10.02.2023).
European Commission, Medical Device Coordination Group: Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices (15.02.2023).
European Court of Justice, InfoCuria: Vorlage zur Vorabentscheidung – Medizinprodukte – Richtlinie 93/42/EWG – Art. 1 Abs. 2 Buchst. a – Definition – Art. 1 Abs. 5 Buchst. c – Anwendungsbereich – Humanarzneimittel – Richtlinie 2001/83/EG – Art. 1 Nr. 2 – Definition des Begriffs ‚Arzneimittel' – Art. 2 Abs. 2 – Anwendbarer Rechtsrahmen – Einstufung als ‚Medizinprodukt' oder als ‚Arzneimittel'" (19.01.2023).
Official Journal of the European Union: Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose (Text with EEA relevance) (02.12.2022).
Official Journal of the European Union: Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (Text with EEA relevance) (02.12.2022).
Riigi Teataja: Medical Device Act (22.12.2022).
Swedish Medical Products Agency:New e-service for safety reporting for medical devices (05.12.2022).
Zakony: Act No. 375/2022 Coll. The Act on Medical Devices and In Vitro Diagnostic Medical Devices (07.12.2022).
Team NB: Team NB Position in Response to MDCG 2022-14 Item Number 17 – 'Certificates under Conditions' (11.11.2022).