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), JUNE 2021

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. They shall be applied after the graduated transitional periods, ranging from six months to five years, have ended for different stakeholders.

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

BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (Germany)
CCP	Committees for the Protection of Persons (France)
ClinO-MD	Ordinance on Clinical Trials with Medical Devices (Switzerland)
EC	European Commission
EMA	European Medicines Agency
EMDN	European Medical Device Nomenclature
EURL	EU Reference Laboratories
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
MedDo	Swiss Medical Devices Ordinance (Switzerland)
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MPDG	Medizinprodukte-Durchführungsgesetz (Germany)
MPEUAnpG	Medizinprodukte-EU-Anpassungsgesetz (Germany)
MPG	Medizinproduktegesetz (Germany)
MRA	Mutual Recognition Agreement
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
UDI	Unique Device Identification

3 The Date of Application of the MDR has arrived

After four years of transition period followed by a one-year delay due to the pandemic, the date of application of the medical device regulation 2017/745 was reached on 26 May 2021. Announcing the application of the MDR, the European Commission (EC) issued a Q&A document outlining some of the changes the MDR introduces and delineating that some provisions will not be in place until 2025. At the date of application of the MDR, twenty notified bodies (out of fifty applicants) are designated, more than sixty guidance documents are published, and EUDAMED is partially available. The grace period for the legacy MDD/AIMDD products, which lasts until 26 May 2024, has started and only applies as long as those products comply with the conditions laid out in the MDR.

In another notice, the EC informed stakeholders that the mutual recognition and related trade facilitating effects for medical devices between the EU and Switzerland ceased to apply. Since the Mutual Recognition Agreement (MRA) between Switzerland and the EU was not updated, Switzerland is now treated as a third country from an EU perspective and vice versa.

4 Implementing and delegated acts & guidelines

4.1 Updated implementation rolling plan and ongoing MDCG guidance document overview

Another update of the MDR and IVDR implementing measures rolling plan was issued in April 2021. The MDCG issued a revised overview of the ongoing guidance documents the different subgroups are working on in 2021. Information on the following consultations was made available:

- Medical devices – online manuals replacing paper instructions
- Medical devices - reclassification of products without an intended medical purpose
- Medical devices – EU rules on setting up and maintaining the EUDAMED database

4.2 Expert panels are accepting submissions for the consultation procedure

On 1 April 2021, the EC informed that the expert panels in the field of medical devices accept submissions from notified bodies for the clinical evaluation consultation procedure.

4.3 Standardisation request: CEN and CENELEC accept the European Commission's mandate

In April 2021, the EC's revised Implementing Decision on a standardisation mandate to CEN and CENELEC in support of the MDR and IVDR was published and sent to the two relevant European standardisation organisations. On 12 May 2021, CEN and CENELEC informed the EC that their Technical Boards had accepted the standardisation request, which marks the harmonisation of standards under the Regulations IVDR and MDR. As from now, standards can be cited in the EU Official Journal against IVDR and MDR, offering the presumption of conformity.

4.4 First version of European Medical Device Nomenclature (EMDN) made public

The first version of the European Medical Device Nomenclature (EMDN), was released on 4 May 2021. The EC launched the hosting platform of the European Nomenclature for Medical Devices in the Italian and English language versions. The English version is currently undergoing a linguistic consultation.

The EMDN will be used to register medical devices in EUDAMED. It will play a key role in device documentation and technical documentation, post-market surveillance, vigilance, and post-market data analysis.

4.5 New MDCG guidance on standardisation for medical devices published

In this document, the MDCG provides information on different aspects of standardisation for medical devices, such as the general framework for harmonised European standards (including the relationship between harmonised European standards and European legislation, the Z Annexes), the concept of "state of the art", and the governance structure for standards in the medical device sector.

4.6 MDCG issues question and answer document on clinical investigations under MDR

MDCG 2021-6 is intended for sponsors of clinical investigations of medical devices conducted within the scope of the MDR. It explains the general differences and improvements related to clinical investigations under the MDR compared with the medical device directives and answers what constitutes a substantial modification.

4.7 MDGC issues document on certification of class D in vitro diagnostic medical devices during the transition period

MDCG 2021-4 outlines how the provisions of the IVDR can be applied during the transition period, which means before the date of application on 26 May 2022 in the absence of the required expert panel and/or EU reference laboratories (EURL).

4.8 European Commission introduces UDI helpdesk

A new UDI helpdesk is available to support economic operators in implementing the requirements introduced by the new UDI system. The website includes Q&A sections covering different topics such as UDI assignment, labelling, registration of devices and the use of the EMDN. The helpdesk enables economic operators to ask questions about the UDI system by sending written requests.

4.9 Updated guidance on basic UDI-DI and changes to UDI-DI

Revision 4 of the MDCG guidance on basic UDI-DI and changes to UDI-DI includes the following changes:

- Section - The Basic UDI-DI:
- *Deletion of the word 'group' in paragraph 3.*
- Section – Changes of UDI-DI:
  Point 3 on maximum number of reuses added.

4.10 MDCG position paper on UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers

The MDCG provides detailed information about UDI implementation for eyeglass and lens manufacturers in a new position paper.

4.11 MDCG guidance on custom-made devices under MDR

The MDCG has published a guidance document on custom-made devices and considerations on adaptable medical devices under the MDR. This document describes the MDR requirements for manufacturers of custom-made devices, and contains clarifications for so-called intermediate products intended for the manufacture of custom-made devices.

4.12 Commission issues new factsheet for Class I medical devices

The EC published a new factsheet for Class I medical devices manufacturers, outlining the regulatory requirements and changes introduced by the MDR.

4.13 EMA publishes revision of FAQ document on consultation procedure

The European Medicines Agency (EMA) updated its FAQ document on the consultation procedure for an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device as well as the corresponding application forms.

5 EUDAMED

5.1 Update on EUDAMED implementation timeline – next modules not available before September

The EC has officially confirmed another delay to the previously announced timeline. The implementation of the two modules, UDI/device registration and certificates and notified bodies, is now expected for September 2021 instead of May 2021. Those two modules are already accessible in the EUDAMED playground.

Compliance with MDR requirements in connection with EUDAMED will not be mandatory until all six modules of the database are ready.

5.2 MDCG document describes administrative practices and alternative technical solutions until EUDAMED is fully functional

Until EUDAMED is fully operational, the relevant provisions of Directives 90/385/EEC and 93/42/EEC continue to apply to fulfil the obligations laid down in the provisions of Article 123(3)(d). MDCG 2021-1 aims to provide a harmonised approach by outlining administrative practices and alternative technical solutions to exchange information until the database is ready.

5.3 MDCG publishes clinical investigation application/notification forms under the MDR to be used in the absence of EUDAMED

As EUDAMED is not yet operational, the MDGC has published a set of clinical trial application/notification documents. They are intended to support clinical trial procedures in relation to the MDR in the absence of the EUDAMED module on clinical investigations:

- Clinical investigation - application/notification form under the MDR
- Addendum to the clinical investigation application/notification form for:
    - Additional investigational device(s) (section 3)
    - Additional comparator device(s) (section 4)
    - Additional investigation site(s) (section 5)
- Clinical investigation supporting documents - Appendix of documents to attach
- Checklist of general safety and performance requirements, standards, common specifications and scientific advice

The clinical trial application/notification form contains, as far as possible, the same data fields as EUDAMED. In the absence of EUDAMED, the EU-wide unique identification number for a clinical trial, to be used for all relevant communication related to that clinical trial, will be the CIV-ID. It is recommended to check with the Member State in which the clinical trial is to be conducted to see if there are any additional specific national requirements. These documents will be withdrawn once the EUDAMED clinical trial module is fully operational.

6 Notified body designation

6.1 20 notified bodies designated under the MDR, four under the IVDR

20 notified bodies are designated under the MDR and four under the IVDR. According to the latest overview of notified bodies at each stage of the designation process, there could be another nine notified bodies designated under the MDR within the next nine months. That would bring the total to 28 under the MDR. The document also reveals that only one more notified body is expected to be designated under the IVDR in the same timeframe.

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

- Eurofins Expert Services Oy, Finland

7 Implementation activities on national levels

7.1 France: New decree simplifies operations of clinical investigation authorisation bodies

A newly issued decree introduces the following changes to the operations of the Committees for the Protection of Persons (CPP), the French bodies authorising clinical investigations with medical devices:

- The functioning of CPPs is simplified by eliminating the use of the compulsory expertise of an independent ethics committee.
- The decree specifies certain procedures (for example, the procedures applicable in a telephone or audiovisual conference).

7.2 Germany: New Medizinprodukte-Durchführungsgesetz in force

To ensure the implementation of the MDR and IVDR and the interaction with the highly differentiated national provisions in Germany, the Medizinprodukte-EU-Anpassungsgesetz (MPEUAnpG) was promulgated in the Federal Law Gazette on 22 May 2020. It includes the Medizinprodukte-Durchführungsgesetz (MPDG), replacing the previous Medizinproduktegesetz (MPG) and serves to implement and supplement national provisions of the MDR. The latest change to the Medizinprodukterecht-Durchführungsgesetz was published on 21 May 2021 and includes, among other things, details to the notification requirements for sponsors of clinical investigations. The BfArM published updated forms for reporting of serious adverse events (SAE) and device defects (DD) in the context of a clinical trial according to the MDR and the MPDG.

7.3 Germany: Ministry of Health informs about national provisions until EUDAMED is fully operational

The Federal Ministry of Health has published a notice on the transition period until EUDAMED is fully operational. The notice lists in table form in detail how the obligations and requirements mentioned in Article 123(3)(d) of the MDR are to be fulfilled in the absence of EUDAMED.

7.4 Ireland: HPRA issues new guidance and forms for clinical investigation applications

HPRA issued a guidance document to provide an overview of legislation relevant to clinical investigations involving medical devices and details on submitting applications to conduct clinical investigations in Ireland. The document includes details on the contingency measures the HPRA uses pending the deployment of the respective module of EUDAMED. A new notification form is also available on HPRA's website.

7.5 Norway: MDR and IVDR transferred into Norwegian law

The MDR and IVDR have been transferred into Norwegian law through law No 37 of 7 May 2020 on medical devices (lov om medisinisk utstyr). On 9 May 2021, the Norwegian council of state passed a new regulation (forskrift om medisinsk utstyr) that supplements this law and regulates the different implementation dates of the MDR and the IVDR and the national provisions.

7.6 Northern Ireland: Updated guidance on clinical investigation as MDR takes effect in Northern Ireland

The MHRA has updated its guidance on clinical investigations of medical devices in Northern Ireland, where the MDR took effect on 26 May 2021. Sponsors need to notify the MHRA, but the notification requirements are determined by the MDR (including reporting of SAE according to MDG 2020-10/2).

7.7 Turkey: Continuation of Turkey's integration into the EU market

A letter from the EC to the MDCG confirms that the final steps to update the Customs Union for medical devices between the European Union and Turkey have been completed, ensuring Turkey's further integration into the EU market and the facilitation of trade. A similar alignment allowing the continuation of the EU-Turkey Customs Union for in vitro diagnostic medical devices is to follow.

7.8 Switzerland: Medical Devices Ordinance and its amending enactment in force

The revised Swiss Medical Devices Ordinance (MedDo) entered into force on 26 May 2021. The revised MedDo is composed of the version adopted on 1 July 2020 (which was based on a fully updated MRA) and the amending enactment published by the Swiss Federal Council on 19 May 2021. The new Ordinance on Clinical Trials with Medical Devices (ClinO-MD) also applies since 26 May 2021 and replaces the previous regulation on clinical trials with medical devices. It introduces new requirements and changes to the authorisation practice.

On 14 April 2021, the Federal Council opened the consultation on the IvDO and the corresponding amendments to the ClinO-MD.

8 IVD-specific issues

8.1 Team NB adopts position paper on conformity assessment for Class D devices

Following the publication of MDCG 2021-4, Team NB published a position paper to outline the approach NBs will follow to perform conformity assessments of class D devices, in the absence of EURLs and considering the delay of the IVD expert panel.

9 Miscellaneous

9.1 EU – Team NB publishes annual survey results

Team NB conducted an annual industry survey among its members in 2020. The results show that a high number of certificates will expire in 2024, confirming the raised concerns of notified body capacity issues in 2024.

10 Sources

European Commission: Ongoing guidance development and deliverables of MDCG Subgroups – March 2021 (March 2021).
European Commission: OVERVIEW OF NBs AT EACH STAGE OF THE PROCESS (04.03.2021).
European Commission: Medical Devices – EUDAMED (retrieved 11.03.2021).
European Commission: Medical devices - reclassification of products without an intended medical purpose (April 2021).
European Commission: Medical Devices - Expert Panels (retrieved 01.04.2021).
European Commission: Updated Implementation Rolling Plan - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (09.04.2021).
European Commission: COMMISSION IMPLEMENTING DECISION of 14.4.2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (14.04.2021).
European Commission: Medical devices – online manuals replacing paper instructions (27.04.2021).
European Commission: Factsheet for Class I Medical Devices (28.04.2021).
European Commission: Update of the EU-Turkey Customs Union for medical devices (25.05.2021).
European Commission: Medical devices – EU rules on setting up and maintaining the EUDAMED database (26.05.2021).

European Commission: Questions & Answers: Application of Regulation on Medical Devices – EU rules to ensure safety of medical devices (26.05.2021).
European Commission: Public health: Stronger rules on medical devices (26.05.2021).
European Commission: Commission publishes information notice on the status of the EU – Switzerland Mutual Recognition Agreement for Medical Devices (26.05.2021).
European Commission, Medical Device Coordination Group: MDCG 2021-3 Questions and Answers on Custom-Made Devices & considerations on Adaptable medical devices and Patient-matched medical devices (15.03.2021).
European Commission, Medical Device Coordination Group: MDCG 2021-4 Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746 (MDCG, 09.04.2021).
European Commission, Medical Device Coordination Group: MDCG 2021-5 Guidance on standardisation for medical devices (16.04.2021).
European Commission, Medical Device Coordination Group: MDCG 2021-6 Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation (22.04.2021).
European Commission, Medical Device Coordination Group: MDCG 2018-1 Rev.4 Guidance on BASIC UDI-DI and changes to UDI-DI (27.04.2021).
European Commission, Medical Device Coordination Group: MDCG 2021-1 Rev.1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional (04.05.2021).
European Commission, Medical Device Coordination Group: MDCG 2021-08 Clinical investigation application/notification documents (21.05.2021).
European Commission, Medical Device Coordination Group: MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers (27.05.2021).
European Medicines Agency: Questions & Answers on the consultation procedure to the European Medicines Agency by notified bodies on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device (30.03.2021).
France, Légifrance: Décret n° 2021-301 du 19 mars 2021 modifiant certains articles du titre II du livre Ier de la première partie du code de la santé publique (partie réglementaire) relatif aux recherches impliquant la personne humaine (19.03.2021).
Germany, BfArM: Meldung schwerwiegender unerwünschter Ereignisse (SAE) und Produktmängel (DD) im Rahmen einer klinischen Prüfung gemäß MDR und MPDG (26.05.2021).
Germany, Bundesministerium für Gesundheit: Bekanntmachung des Bundesministeriums für Gesundheit nach § 97 Absatz 1 Satz 2 und Absatz 2 des Medizinprodukterecht-Durchführungsgesetzes (MPDG) zur Regelung des Übergangszeitraums bis zur vollen Funktionsfähigkeit der Europäischen Datenbank für Medizinprodukte nach Artikel 33 der Verordnung (EU) 2017/745 vom 26. Mai 2021 (26.05.2021).
Ireland, HPRA: Guide to Clinical Investigations Carried Out in Ireland (12.03.2021).
Ireland, HPRA: Notification of a Clinical Investigation of a CE Marked Medical Device (Article 74 MDR) (20.05.2021).
Norway, Lovdata: Forskrift om medisinsk utstyr (09.05.2021).
Switzerland, Swissmedic: New requirements and changes to authorisation practice as of May 2021 (retrieved 09.04.2021).
Switzerland, Bundesamt für Gesundheit: Mehr Sicherheit bei Medizinprodukten: Bundesrat eröffnet Vernehmlassung für Ausführungsrecht In vitro Diagnostika (14.04.2021).
Switzerland, Fedlex: Medizinprodukteverordnung (MepV) (26.05.2021).
Switzerland, Fedlex: Medizinprodukteverordnung (MepV) Änderungen vom 19. Mai 2021 (19.05.2021).
Switzerland, Fedlex: Verordnung über klinische Versuche mit Medizinprodukten (KlinV-Mep) (26.05.2021).
Team NB: Team-NB Notified Bodies considerations on conformity assessment for class D devices (19.05.2021).
Team NB: PRESS RELEASE Team-NB sector survey 2020 (14.04.2021).
UK, MHRA: Notify the MHRA about a clinical investigation for a medical device (25.05.2021).