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), AUGUST 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

ANSM	Agence nationale de sécurité du médicament et des produits de santé, France
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (Germany)
CECP	Clinical Evaluation Consultation Procedure
CS	Common Specifications
EC	European Commission
EMA	European Medicines Agency
EURL	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
MEB	Medicines Evaluation Board, Netherlands
MRA	Mutual Recognition Agreement
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
UDI	Unique Device Identification
QMS	Quality Management System

3 Implementing and delegated acts & guidelines

3.1 First harmonised standards under MDR and IVDR are now available

The first standards under the MDR and IVDR have been harmonised. These standards mainly relate to sterility and biocompatibility. Commission Implementing Decision 2021/1182 includes references to five harmonised standards for medical devices drafted in support of the MDR. Likewise, Commission Implementing Decision 2021/1195 contains references to five harmonised standards for medical devices drafted in support of the IVDR. Compliance with a harmonised standard confers a presumption of conformity with the corresponding requirements in the IVDR since the date of publication in the Official Journal on 20 July 2021.

3.2 Another update of implementing rolling plan and overview of ongoing guidance documents issued

Another update of the overview of the ongoing guidance documents the different MDCG subgroups are working on, and another update of the MDR and IVDR implementing measures rolling plan were issued in June 2021. The updated plan foresees, among other things, that the adoption of the common specifications for products without a medical purpose is now expected in the third quarter of 2021.

Under the MDR, new implementing acts are due to be published for:

– Common specifications (CS) for Annex XVI products without an intended medical purpose such as dermal fillers and liposuction equipment; and

Under the IVDR, implementing acts are due to be published regarding:

– Rules to facilitate the EU reference laboratories (EURLs) fulfilling their tasks and ensure that they comply with IVDR criteria;
– Fees for EURL services; and
– CS for certain IVDs in class D. These effectively mandatory technical standards are intended to ensure all parties (manufacturers, notified bodies, expert panels, and EURLs) have the same expectations of these products.

3.3 MDCG document on clinical investigation ID in the absence of the respective EUDAMED module

The MDCG issued information on generating European tracking to identify clinical investigations according to the MDR without the respective EUDAMED module. The purpose of generating a CIV ID is to create a tracking number that can be used to identify a specific clinical trial. In addition, a CIV ID facilitates communication between sponsors and competent authorities and competent authorities in the different Member States.

3.4 MDCG guidance provides a non-exhaustive list of implantable medical device types

MDCG 2021-11 provides a non-exhaustive list of implantable medical device types to assist manufacturers in assigning an appropriate term to this requested information.

3.5 MDCG guidance on integrating UDI into an organisation's QMS

In a new document, the MDCG outlines how to implement the MDR / IVDR requirements related to the Unique Device Identification (UDI) system within the Quality Management System (QMS). This applies to the QMS of a manufacturer, an economic operator or a person assuming the manufacturer's obligations according to Article 16(1) MDR/IVDR and Article 22(4) MDR.

3.6 MDCG guidance on the quality management system to be established by distributors and importers relabelling or repackaging devices

MDCG 2021-23 outlines the requirements importers and distributors of medical devices must fulfil if they repack or relabel medical devices or translate the information supplied with the product. In addition, it describes

what kind of oversight notified bodies must provide in these circumstances, mainly focusing on activities performed by notified bodies and the quality management system they are expected to assess.

3.7 MDCG document clarifies status of IMDRF appendixes on UDI under MDR

The EC had launched a consultation on Annexes E to I of the document IMDRF UDI application guidance N48 in April 2020, given a possible adoption at EU level. MDCG 2021-10 intends to clarify how certain principles and examples outlined in N48 Appendixes E-I apply under the MDR/IVDR.

3.8 MDCG guidance clarifies the involvement of an expert panel for new high-risk IVDs

MDCG 2021-11 explains that a notified body has to consult with an expert panel on the performance evaluation report of an IVD if no device of that type has been certified yet (either under Directive 98/79/EC or under Regulation (EU) 2017/746) and if no common specifications are available for that device.

3.9 EMA updates Q&A document on devices incorporating a medicinal substance

The EMA has updated its Q&A document on marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the MDR and IVDR.

3.10 EMA publishes guidance on quality documentation for medicinal products when used with a medical device

The EMA published the document *Guideline on quality documentation for medicinal products when used with a medical device* on its website on 23 July 2021. This guideline is applicable from 1 January 2022. It describes the information that should be included in the quality section of a marketing authorisation dossier for a medicinal product when used with a medical device or device part.

4 EUDAMED

4.1 Update on EUDAMED implementation timeline

At the beginning of July 2021, the European Commission communicated an update of the gradual implementation of EUDAMED. The module on UDI/device registration and the module on Certificates and Notified Bodies will become available in September 2021 (except for the mechanism for scrutiny and the clinical evaluation consultation procedure (CECP) functionalities). Afterwards, the remaining modules and the mechanism for scrutiny and the CECP will be released when EUDAMED is fully functional. Furthermore, the information states that the vigilance and CI/PS modules will not be released until EUDAMED is fully functional. However, whether or not the market surveillance module will be released before EUDAMED is fully functional has not yet been decided.

4.2 MDCG issues document on EUDAMED registration requirements for certain actors

This document answers questions related to the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers who are subject to the obligations of Article 31 of the MDR and/or Article 28 of the IVDR. It also clarifies the cases where an actor ID is issued instead of an SRN.

4.3 Updates to technical documentation regarding EUDAMED available

The European Commission has made updates to the technical documentation regarding EUDAMED available on its website. The following documents are affected by the updates:

- UDI device data dictionary: This document defines the information provided in EUDAMED module "UDI device registration".
- M2M data exchange services definition, service entity model XSD and xml samples: If the manufacturer is to register/download more than 1000 products, the machine-to-machine (M2M) automatic data

exchange system is recommended. These three documents are required for M2M data exchange for economic operators.

4.4 Revised version of FAQ document on actor module published

As part of its website on medical devices and EUDAMED, the European Commission set up a particular page on the actor registration module. In addition, it published a question and answer document on this topic. It explains that the Swiss competent authority will not be registered in EUDAMED as there is no longer a mutual recognition agreement between the EU and Switzerland for medical devices. Therefore, Swiss manufacturers can only register in EUDAMED via their authorised representative in the EU, as Switzerland is only available in the non-EU countries list.

Turkish national competent authorities will be registered in EUDAMED by the end of September 2021. Turkish operators (including manufacturers, producers of systems and treatment units, authorised representatives and importers) established in Turkey will be able to submit applications for registration of operators from the end of September 2021.

5 Notified body designation

5.1 22 notified bodies designated under the MDR, six under the IVDR

22 notified bodies are currently designated under the MDR and six under the IVDR.

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

- KIWA CERMET ITALIA S.P.A.
- Eurofins Product Testing Italy S.r.l.

The following additional NBs with IVDR designation are listed in NANDO:
- DEKRA Certification B.V, Netherlands
- GMED SAS, France

6 Implementation activities on national levels

6.1 Italy: MOH issues circular on clinical investigations and vigilance under MDR

National provisions concerning medical devices are governed by Law of 22 April 2021, n. 53 in Italy. In recently issued circulars, the Italian MOH informs about the national provisions that apply to clinical investigations of medical devices under the MDR and vigilance requirements in the absence of EUDAMED.

6.2 France: ANSM issues guide for medical devices with ancillary medicinal substance

The French Competent Authority (ANSM) has released a guide for notified bodies and manufacturers on the procedure to be followed and the documentation necessary to consult ANSM on the quality, safety and benefit/risk profile associated incorporating an ancillary medicinal substance in a medical device.

6.3 Netherlands: MEB informs about consultation procedure for devices containing a medicinal product

In the Netherlands, the Medicines Evaluation Board (MEB) can act as the competent authority in the consultation procedure applicable to medical devices containing a substance. The MEB recently provided additional information about the procedure for medical devices to prepare for the workload.

6.4 Romania: Ordinance to implement national provisions of MDR in force

Government Emergency Ordinance no. 46/2021 entered into force on 11 June 2021, establishing the institutional framework and measures for implementing the MDR in Romania.

6.1 Germany: BfArM revised its FAQ concerning clinical trials

Following the date of application of the MDR, the BfArM has revised its frequently asked questions (FAQ) section concerning clinical trials.

6.2 Ireland: Medical device regulation giving full effect to MDR and detailing national provisions

Alongside the MDR, the Irish Medical Device Regulations 2021 (S.I. No. 261 of 2021) (2021 Regulations) came into operation on 26 May 2021. The law sets out the Irish position on the processing of single-use devices and clinical investigations.

7 IVD-specific issues

7.1 MDCG publishes joint implementation and preparedness plan for IVDR

The recently published *Joint implementation and preparedness plan for Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)* outlines the priorities for implementing the IVDR and, at the same time, serves to monitor the implementation progress.

7.2 MDCG issues explanatory note on IVDR codes

The MDCG issued a guidance document on assigning codes to in vitro diagnostic medical devices, explaining the different levels of codes and how they should be used. The codes are used to describe the scope of a notified body's designation and describe the individual qualification of notified body staff members.

7.3 New forms for NB to submit for designation under MDR and IVDR

In July 2021, the MDCG issued four new forms for notified bodies to fill in when applying to be designated under the Medical Device and IVD Regulations.

8 Miscellaneous

8.1 Corrigendum of IVDR published in Official Journal

A corrigendum to the IVDR was published in the Official Journal of the European Union, correcting translation errors in different language versions (including German, French, Italian, and more). These amendments were editorial; there are no major IVDR structural changes.

8.2 Corrigendum to the MDR published in the Official Journal of the European Union

On 8 July 2021, a corrigendum to Regulation (EU) 2017/745 on medical devices (MDR) was published in the Official Journal of the European Union. Among others, the German, French, Italian and Dutch versions of the MDR were corrected. The correction of the German version mainly corrects translation errors and article numbers.

8.3 Medtech Europe commissioned legal opinion on EC's position on Swiss MRA

MedTech Europe commissioned Sidley Austin to develop a legal opinion on the commission's position on discontinuing the mutual recognition agreement (MRA) between the EU and Switzerland. The EC informed about the discontinuation of the mutual recognition agreement (MRA) between Switzerland and the EU in a notice to stakeholders. According to the legal opinion, this retrospective withdrawal of mutual recognition of legacy devices contradicts EU law, the MRA, and WTO law.

8.4 First opinion of the scientific panels in the field of medical devices published

On 15 June 2021, the first opinion of the expert panel was published in the context of the consultation procedure related to clinical evaluation (CECP). The expert panel challenged the adequacy of the clinical evidence assessment by the notified body of the Ivory Dentin Graft, a Class III implant intended for use in a variety of surgical procedures in maxillofacial surgery and dentistry.

The opinion is temporarily removed from the expert panel web page following a request from the notified body.

8.5 MDCG guidance on performance evaluation of SARS-COV2 IVDs

The MDCG has published a guidance document on evaluating the performance of SARS-COV2 IVDs. The document applies to IVDs in the context of the current IVD Directive and should form the basis for common specifications to be adopted under the IVDR.

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