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. They shall be applied after the graduated transitional periods, ranging from six months to five years, have ended for different stakeholders; thereby setting the general application date to spring 2020 for the MDR and spring 2022 for the IVDR. The transition timelines are illustrated in this overview issued by the European Commission.

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

CAMD	Competent Authorities for Medical Devices
EC	European Commission
EMA	European Medicines Agency
EMDN	European Medical Device Nomenclature
EURL	EU reference laboratories
GMDN	Global Medical Device Nomenclature
IMDRF	International Medical Device Regulators Forum
IVDR	In Vitro Diagnostics Regulation (EU) 2017/746
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation (EU) 2017/745
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body

3 Second MDR/IVDR corrigenda published in EU Official Journal

The plenary session of the European Parliament approved the second Corrigenda on 17 December 2019. The publication in the EU Official Journal followed on 27 December 2019:

– IVDR:https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746R(03)
– MDR: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745R(02)

With the publication, the corrigenda took immediate effect.

The MDR Corrigendum is especially relevant because it provides important clarifications regarding the range of medical devices eligible for the MDR grace period, which now includes all upgraded class I devices and extends beyond the 26 May 2020 date of application and until 26 May 2024.

4 Implementing and delegated acts & guidelines

4.1 Updated version of MDR & IVDR implementation rolling plan issued

In December 2019, the implementation rolling plan was updated, indicating that the following implementing acts are expected to be finalized and published in the first quarter of 2020:

(MDR)

– The Common Specifications on the reprocessing of single-use medical devices are currently undergoing the formal adoption procedure. The rolling plan states that if the common specifications are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions.

A decision regarding the request for development of standards to the European Standardisation Organisations is expected by Q1 2020, as the draft mandate is currently undergoing the adoption procedure.

Guidance related to the applicability of certain MDR provisions in the absence of Eudamed is in progress and results are expected in Q1/Q2 of 2020 (see 5.1).

(IVDR)

– Implementing Act outlining the rules to facilitate application of IVDR Article 100(2) listing the tasks of EU reference laboratories (EURL) and the rules to ensure compliance with criteria for an EURL listed in IVDR Article 100(4).
– Implementing Act defining the fees for the advice/testing activities performed by EURL.
– Common Specifications for IVD Class D in the context of the scrutiny mechanism for high risk devices.

4.2 Documents reveal ongoing guidance development within MDCG subgroups

The Medical Device Coordination Group (MDCG) has published a document outlining its plans for publishing almost 40 further guidance documents (not an exhaustive list), indicating that most of these documents will be endorsed in the next few months. The document on planned meetings of MDCG subgroups sheds light on future meetings and when announced guidance documents will be endorsed. In all, 31 meetings are scheduled until mid-December 2020, with only 14 meetings scheduled before the DoA of the MDR on 26 May 2020. The agenda reveals that guidance for some topics will be available only after the MDR applies.

4.3 MDCG 2019-13 Guidance on sampling of devices for the assessment of the technical documentation

The MDCG endorsed a document outlining the sampling criteria and the use of such criteria for a sampling plan of Class IIa and Class IIb devices under the MDR and Class B and Class C devices under the IVDR. The guidance refers to sampling prior to the issuance of a QMS certificate, sampling during surveillance, qualitative sampling criteria, and information on assessment of the technical documentation.

4.4 MDCG 2019-14 Explanatory note on MDR codes

MDCG 2019-14 is an explanatory note on the codes established by the Commission Implementing Regulation 2017/2185 to describe the scope a notified body is designated to under the MDR. The document supports notified bodies in ensuring that they have the necessary staffing resources to review applications and that the staff assigned are fully competent for the devices which they are required to assess.

4.5 MDCG 2019-15 Guidance notes for manufacturers of class I medical devices

On the topic of class I medical devices in general, document MDCG 2019-15 was published in December 2019, including notes on the conformity assessment procedure for all Class I devices (including reusable, sterile, or with a measuring function).

4.6 MDCG 2019-16 Guidance on cybersecurity for medical devices

The guidance on cybersecurity under MDR and IVDR aligns with the cybersecurity guidance from the International Medical Device Regulators Forum (IMDRF) and outlines all relevant cybersecurity requirements which manufacturers have to fulfil in accordance with Annex I of the MDR and IVDR.

4.7 Updated documents concerning UDI formats published

The European Commission published several documents of the four designated companies on the subject of UDI in December 2019. In particular, four documents from each company pertain to the basic UDI-DI, while four documents pertain to the Human Readable Form (HRI) and Automatic Identification and Data Capture (AIDC) formats.

- GS1 Basic UDI-DI (04/12/2019).
- HIBCC Basic UDI-DI (04/12/2019).
- ICCBBA UDI HRI & AIDC Formats (04/12/2019).
- HIBCC UDI HRI & AIDC Formats (04/12/2019).
- ICCBBA Basic UDI-DI (04/12/2019).
- IFA Basic UDI-DI (04/12/2019).
- IFA UDI HRI & AIDC Formats (Last update: 05/12/2019).
- GS1 UDI HRI & AIDC Formats (Last update: 05/12/2019).

4.8 Commission calls for observers to provide input on medical devices without an intended medical purpose

The European Commission issued a call for applications for observers to join the Annex XVI subgroup of the MDCG. The working group will provide advice on applying the safety and performance requirements described in Annex I of the MDR, describe the obligation of companies under Chapter II, and develop guidance on the requirements for devices listed in Annex XVI.

4.9 EMA updates recommendation on consultation procedure for ancillary medicinal substances in medical devices under the MDR

The MDR requires a notified body to seek an opinion from a competent authority on the quality and safety of medicinal substances incorporated in medical devices that have an action that is ancillary to the action of the devices. The European Medicines Agency (EMA) is the competent authority for substances that are derived from human blood or human plasma or that fall under the scope of the centralised procedure. It recently updated its recommendations on the consultation procedure. Notified bodies may also consult EMA for other substances—e.g. if the Agency has already evaluated a medicine containing the same active substance.

5 Eudamed

5.1 Possible interim scheme in absence of Eudamed announced

Following the announcement of the postponement of Eudamed's launch until May 2022, the Competent Authorities for Medical Devices (CAMD) executive group released an open letter sharing its concerns about this development. After additional pressure from member states, the European Commission announced at the 9 December EPSCO Council meeting of ministers that it plans to make an actor registration module available by May 2020, confirming that the work to provide guidance (concerning the MDR provisions that will apply in the absence of Eudamed) is ongoing in the implementation rolling plan.

5.2 Information on EMDN nomenclature published

Two documents with information on the future European Medical Device Nomenclature were published in January:

– A document on the current ongoing work, its mapping with GMDN, management of EMDN at the MDCG level
– A document providing information on the CND Nomenclature's background, general principles, structure/grouping hierarchy

5.3 Economic operators are enabled to test newest version of Eudamed modules

Economic operators can test the fourth version of the Eudamed interface in relation to the modules "Registration of Actors" and "UDI". The fourth version of the modules "Registration of Actors" and "UDI" can be tested here since 12 December 2019. The following changes have been made since the last version:

Module "UDI":
– Registration of Standard Devices - Updates on Statuses;
– Registration of Standard Devices - Container Package updates;
– Creating a new version for UDI-DI - Updates in Statuses- providing the Market information;

Module "Registration of Actors":
– Bulk upload (via the User Interface) for Actor registration assessment

6 Notified body designation

6.1 11 notified bodies designated under the MDR, three under the IVDR

The EC had intended to designate 20 notified bodies by the end of the year 2019. The updated implementation rolling plan highlights the aim to designate prior to May 2020 as many notified bodies as possible. Currently, the following NBs with MDR designation are listed in NANDO:
– IMQ (Italy)
– BSI UK (United Kingdom)
– TüV SüD (Germany)
– DEKRA (Germany)
– TüV Rheinland (Germany)
– DARE!! Services (Netherlands)
– BSI Netherlands (Netherlands)
– DEKRA Certification B.V. (Netherlands)
– MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH (Germany)
– DNV GL Presafe AS (Netherlands
– National Standards Authority of Ireland (NSAI) (Ireland)

The total number of notified bodies designated under the IVDR remains at three:

– DEKRA Certification GmbH (Germany)
– BSI Group The Netherlands B.V. (Netherlands)
– BSI Assurance UK Ltd (United Kingdom)

The updated joint-assessment progress report indicates 44 applications for designation under the MDR, and 11 applications under the IVDR have been received until now.

7 Implementation activities on national levels

7.1 Belgium and Denmark give information about new nomenclature to be used for incident reporting

The Belgian FAMHP gives information about the new MIR form and emphasizes the change of nomenclature to be used for incident reporting. Only manufacturers have to use the MIR form; distributors, health care professionals, and patients are not obliged to use the new nomenclature to report incidents.

The Danish Medicines Agency updated its website to include the new MIR form. It also refers to the form when addressing distributors and importers.

7.2 Denmark informs about registration requirements in Denmark

Beginning of January, the Danish Medicines Agency updated the information concerning the requirements to register companies, IVDs, and medical devices in Denmark.

7.3 Netherlands: Information about consultation procedures published

The Medicines Evaluation Board informed that it would only accept applications for consultation procedures submitted under the MDR since the beginning of December. Pending consultation procedures in relation to the MDD should be finalised before the DoA of the MDR—i.e. 26 May 2020. As the current fees for consultation procedures are not cost-effective, the fee for the consultation procedure for a medical device that includes a known active substance will be increased from EUR 4050.00 to EUR 9000.00.

7.4 Switzerland: Swiss Medtech gives information about consequences of current MRA interpretation

In January, Swiss Medtech informed the industry that EC lawyers are interpreting the current Mutual Recognition Agreement (MRA) strictly. The current interpretation assumes that the MRA will cease to apply to medical devices after 26 May 2020. This "worst case scenario", whereby Swiss manufacturers will have to meet the requirements of a third country for all medical devices (MDR and MDD) from 26 May 2020, is therefore realistic from today's perspective.

7.5 Turkey: Proposal submitted to align legislation to MDR

In order to avoid adverse impact on the supply of products, Turkey has submitted its draft proposal to align the legislation with the MDR to the EU Commission. Another proposal to align with the IVDR is supposed to be submitted at a later point.

7.6 UK: The UK has left the EU and introduces new medical devices Bill

The UK has left the European Union but will remain bound by EU laws until 31 December 2020. The MDR will apply in the United Kingdom from 26 May 2020 until the end of this transition period. During the transition period,

- market access will not change.
- the CE marking will continue to be used and recognised in both the UK and EU markets and UK-based industry will not need an authorised representative established in the EU. UK Notified Bodies will continue to carry out conformity assessment activities in the UK. The results of these assessments will continue to be used and recognised for both the UK and EU markets.
- information can continue to be submitted to the MHRA using the existing submission channels. These include reporting serious incidents to the MHRA.

The UK Medicines and Medical Devices (MMD) Bill was laid before parliament in mid-February, starting the debate on how closely it will align with the existing EU legislation.

7.7 UK: MHRA updates guidance on clinical investigations of devices

UK's MHRA published an updated version of the guidance intended to support manufacturers to provide the necessary clinical data to CE mark a device. The update focuses on the decision regarding when a clinical investigation is required and what to consider when deciding whether to run a clinical investigation for a non-CE marked device.

8 Miscellaneous

8.1 Medtech Europe issues call for action due to the implementation status of the MDR

Medtech Europe warns that the regulatory system is not ready to support the transition of lifesaving and life-transforming technologies from the old regulatory regime to the new one. The ways in which medical devices can continue to be placed on the market after 26 May 2020 are difficult to apply due to various challenges:

- Severe lack of notified body capacity
- Lack of expert panel
- Lack of required Delegated and Implementing Acts
- Lack of required EU guidance

MedTech Europe is therefore calling for the European Commission to take steps to ensure that products remain available to patients by widening the applicability of the grace period and by not leaving it to individual member states to cope with requests for national derogations for individual products. A similar call to action has been made by the German trade association BVMed.

8.2 Medical device symbols to be used for EU MDR compliance on ISO website

Medtech Europe issued a guidance document on symbols recommended to be used on medical devices for MDR compliance in May 2019, as the revision of ISO 15223-1 is still ongoing. A number of symbols have been published on the ISO website as part of the ISO 7000 database.

In a recently published paper, Medtech Europe clarifies which symbols developed for labelling requirements introduced by the MDR can potentially be used by the IVD sector.

9 Sources

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