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

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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

AIMDD	Active Implantable Medical Device Directive 90/385/EEC
EC	European Commission
EMA	European Medicines Agency
IMDRF	International Medical Device Regulators Forum
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

3 MDR application date postponed until May 2021

The European Commission (EC) adopted a proposal on 3 April 2020 to postpone the application date of the Medical Devices Regulation (MDR) by one year to 26 May 2021. The European Parliament voted in favour of the proposal on 17 April which was published as Regulation (EU) 2020/561 in the Official Journal on 24 April and took immediate effect.

On 19 May 2020, the EC published guidelines on the adoption of union-wide derogations for medical devices. The possibility for the EC to introduce EU-wide derogations through implementing acts is a feature of Article 59 of the MDR, which was brought into immediate effect by Regulation (EU) 2020/561.

In order to realign the regulatory framework for medical devices to the one-year delay of the MDR, the EC has issued new regulations easing the process for renewing notified body designations before 26 May 2021. Implementing Regulation (EU) No 920/2013 sets out procedural rules and obligations for the renewal of the

designation as notified body to be complied with by the designating authorities of Member States under Directives 90/385/EEC and 93/42/EEC.

Welcoming the amendment, TEAM NB recommends to all manufacturers and stakeholders in the medical device sector to pursue their original plans for transition from the directives MDD/AIMDD to the MDR.
MedTech Europe also welcomes the postponement of the DoA (date of application) of the MDR. It continues to call for the same measure to be implemented for the In Vitro Diagnostic Medical Devices Regulation.

4 Implementing and delegated acts & guidelines

4.1 MDCG issues joint implementation/preparedness plan for the MDR

The European Medical Device Coordinating Group (MDCG) published the joint Implementation/preparedness plan on the new Medical Devices Regulation (EU) 2017/745 (MDR) in mid-March. This document was issued before the legislative procedure to defer the MDR date of application started and refers to the initial date of application in May 2020.

4.2 Implementing decision on standardisation request to CEN and CENELEC

The EC issued implementing decision C(2020) 2532 on the standardisation request made to CEN and CENELEC. It notified them of the request on 18 May 2020. If CEN and CENELEC meet the request, the European standards organisations must submit their draft joint work program to the commission by 30 June and inform the EC of any amendments incorporated thereafter.

4.3 MDCG guidance on 'significant change' restrictions for grace period eligibility

In the second week of March, the long-awaited guidance document on the interpretation of the words 'significant change' was endorsed by the MDCG. MDCG 2020-3 now clarifies the interpretation and provides decision-making criteria and flowcharts to determine whether a change is significant.

4.4 MDCG guidance document on clinical evaluation and demonstration of equivalence

MDCG 2020-5 covers the demonstration of equivalence, based on data related to a device already on the market, for the purpose of CE-marking under the MDR. The document highlights the differences between the MDR and existing guidance Meddev 2.7/1 rev 4 with regard to equivalence.

4.5 MDCG guidance on clinical evidence needed for devices CE-marked under the Directives

MDCG 2020-6 explains clinical data providing 'sufficient clinical evidence' to demonstrate conformity with the relevant General Safety and Performance Requirements in the MDR for legacy devices CE marked under the MDD and AIMDD.

4.6 MDCG guidance on clinical evaluation of medical device software

MDCG 2020-1 provides indications of the level of clinical evidence that notified bodies will expect (quantitatively and qualitatively) from manufacturers of medical device software and offers practical examples for evaluation strategies.

4.7 Post-market clinical follow up (PMCF) plan and evaluation templates

MDCG 2020-7 is a template for the PMCF plan that specifies the methods and procedures, set up by the manufacturer, to collect and evaluate clinical data proactively. MDCG 2020-8 is intended to facilitate the activity of analysing findings from the PMCF plan and documenting the results in the PMCF evaluation report.

4.8 MDCG guidance and form for safety reporting in clinical investigations

MDCG 2020-10/1 explains how safety reporting in clinical investigations of medical devices should be performed under the MDR. The guidance outlines the procedures for safety reporting in clinical investigations in the absence of Eudamed, as the electronic system for such reports will not be available or be fully functional at the date of application of the MDR. MDCG 2020-10/2 is the clinical investigation summary safety report form.

4.9 MDCG guidance on class I transitional provisions under Article 120 MDR

MDCG 2020-2 clarifies the conditions that manufacturers must fulfil to continue to place Class I medical devices certified under the current regime on the EU market until May 26, 2024.

4.10 MDCG guidance on notified body audits during COVID-19 quarantine orders and travel restrictions

MDCG 2020-4 outlines temporary extraordinary measures for notified bodies to follow as long as current travel and social distancing restrictions are in place so as to allow continued availability of safe medical devices on the market. The document applies to audits under the MDD, AIMDD and IVDD, but the principles may apply to audits under the MDR if the availability of devices is affected by COVID-19 restrictions.

4.11 Privacy statement for expert panels on medical devices and IVDs issued

The EC issued ANNEX V – of the call of interest for expert panels outlining the processing of personal data related to expert selection procedures. The document outlines what personal information is collected, for what purpose, and on what legal bases.

4.12Updated guidance on basic UDI-DI and changes to UDI-DI

Document MDCG 2018-1 on the notion of Basic UDI-DI, its use in relevant documentation and the factors triggering UDI-DI changes has been recently updated and published as V3.

4.13 Updated MDCG guidance on implant card and information to be supplied to the patient

The latest revision of MDCG 2019-8 includes changes such as a clarification of the 'MD' symbol (Footnote 7) and a note on language translations provided in the implant card examples (Footnote 9).

4.14 Updated guidance on interpreting Article 54(2)b of the Medical Devices Regulation

The updated MDCG 2019-3 rev 1 clarifies that the full scrutiny procedure, which involves a premarket clinical evaluation consultation procedure, applies only to devices that are new when manufacturers apply for conformity assessment under the MDR. The scrutiny procedure does not apply retrospectively to devices that have already received a conformity assessment under the AIMDD or the MDD.

4.15 Updated MIR form and explanatory documents

An updated manufacturer incident report form was published as the European Competent Authorities and Industry representative organisations agreed to use codified information on incidents (adverse events in IMDRF terminology) for the reporting of incidents in advance of the date of application of the MDR and IVDR.

- Manufacturer incident report 2020
- Changelog file 2020
- Manufacturer incident report for importing XML file with Adobe Professional 2020
- Questions and Answers document regarding the Implementation of the new Manufacturer Incident Report (MIR) Form

4.16 Updated ongoing guidance development within MDCG subgroups issued

In October 2019, the EC prepared a document listing the various guidance documents being prepared by the different MDCG subgroups, including an indication of the status of the planned approval for each document. The document was then updated again in December 2019. As this is a living document, a further update was made in May 2020.

5 Eudamed

5.1 New timetable for release of database in modules

After the one-year postponement of the MDR application date, the EC stated that it would begin making some Eudamed modules available next year. The new timeline sets the new date for the actor registration module to March 2021, at the latest. The modules for unique device identification (UDI)/device registration and certificates/notified bodies will follow as soon as they are functional, which the Commission said could be done by May 2021.

6 Notified body designation

6.1 14 notified bodies designated under the MDR, three under the IVDR

The updated state of play of joint assessments of notified bodies was published mid-March, reporting that 40 on-site assessments had been completed under MDR. Currently, the following NBs with MDR designation are listed in NANDO:

- National Standards Authority of Ireland (NSAI) (Ireland)
- IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. (Italy)
- BSI Assurance UK Ltd (United Kingdom)
- TÜV SÜD Product Service GmbH Zertifizierstellen (Germany)
- DEKRA Certification GmbH (Germany)
- TÜV Rheinland LGA Products GmbH (Germany)
- DEKRA Certification B.V. (Netherlands)
- MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH (Germany)
- MDC MEDICAL DEVICE CERTIFICATION GMBH (Germany)
- DARE!! Services B.V. (Netherlands)
- CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. (Hungary)
- DNV GL Presafe AS (Norway)
- BSI Group The Netherlands B.V. (Netherlands)
- Intertek Medical Notified Body AB (Sweden)

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

7 Implementation activities on national levels

7.1 Denmark: DKMA reveals plans for a Danish database for medical devices

The Danish Medicines Agency (DKMA) updated its strategy to ensure the effective implementation of new EU Regulations. The strategy includes a Danish database, linked to Eudamed in the future, for the active monitoring of the safety related to the use of medical devices.

7.2 Denmark: Enhanced reporting requirements for healthcare professionals in place

The Danish Medicines Agency (DKMA) has introduced enhanced reporting requirements for medical devices. The requirements oblige healthcare professionals to report details of all incidents linked to products selected for enhanced reporting as announced on the DKMA website.

7.3 Finland: Legislation to support MDR & IVDR implementation drafted

The Finnish draft supplementary legislation was published for comments in January 2020. The text creates a new Medical Device Act with provisions complementing the MDR such as language requirements, equipment investigations, powers and mandate of FIMEA (Finish Medicines Agency).

7.4 Germany: DIMDI makes changes to the medical devices information system (MPI)

Due to the postponed date of application of the MDR, the work on adapting the Medical Devices Information System (MPI) to the MDR was consolidated. Applications for clinical trials are based on the current legislation. A changed order of the forms is already available, as well as additional and improved help texts.

7.5 Switzerland: Revised Swiss medical device legislation to be aligned to new MDR date of application

Switzerland's aim is to move in sync the EU legislation and, therefore, it will defer enforcing the revised Swiss medical device legislation by one year to 26 May 2021. The IVDR is not affected by the postponement.

8 IVD-specific issues

8.1 Common technical specifications for IVDs amended

In order to reflect the evolved state-of-the-art, changes in clinical needs, new scientific knowledge and new types of devices on the market, Commission implementing decision (EU) 2020/350 has amended decision 2002/364/EC. The amendment changes:

– the definitions of first-line assays and confirmatory assays,
– the testing requirements for human immunodeficiency (HIV) and hepatitis C virus (HCV) rapid tests, and confirmatory as well as supplementary assays.

9 Miscellaneous

9.1 EMA to form medical devices focus group for MDR/IVDR implementation

The EMA plans to set up an informal medical device focus group to help with the implementation of the EU Regulations on medical devices and IVDs in relation to combined advanced therapy medicinal products (ATMP).

9.2 Team NB issues position paper on documentation requirements for combination products

TEAM-NB published a position paper on documentation requirements for drug/device combination products, focusing on products that fall under the scope of Article 117 of the MDR.

9.3 Medtech Europe issues position paper on the use of state-of-the-art standards in the absence of harmonised standards

Medtech Europe issued a position paper to explore alternative solutions to in the absence of harmonised standards under the MDR.

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