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.

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

CCMO	Central Committee on Research Involving Human Subjects (Netherlands)
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
EC	European Commission
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
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
SRN	Single Registration Number
UKCA	UK Conformity Assessment

3 Implementing and delegated acts & guidelines

3.1 European Commission has updated the agenda for the medtech working groups

The European Commission (EC) has updated the agenda for the medtech working groups within the Medical Device Coordination Group (MDCG) which are working on guidance and structures to help with the implementation of the MDR and IVDR.

3.2 MDCG updates list of ongoing guidance development

At the end of October, the MDCG published the timetable of expected readiness of 46 new documents, and most are unlikely to be ready until early 2021. Twenty of the 46 documents are due to be completed within the next two months, another four by the end of March 2021, and yet another nine by the end of 2021.

3.3 New draft standardisation request for MDR and IVDR published

The EC has published a third draft request for standards needed under the MDR and IVDR. This time the deadline for the adoption of these harmonised standards is 27 May 2024. Comments from member states and expert entities were received until 13 November 2020. The controversial wording in Annex III (it was one of the reasons CEN and Cenelec rejected the May 2020 request), which required all definitions of international standards to be word-for-word consistent with any European legislation definitions for a given term, has been removed. If the standards bodies accept this third draft request, the next step is for CEN and Cenelec to prepare a work program and submit it to the Commission.

3.4 MDCG guidance on IVDR classification rules published

The MDCG has published a guidance document on the classification of IVDs under the new IVD Regulation, providing clarifications on the seven IVD classification rules, as set out under Annex VIII of the IVDR. The document provides the rationale for the rules and examples for illustrative purposes.

4 EUDAMED

4.1 More information on EUDAMED actor registration module available

The EC has added a new section to the EUDAMED information website, providing additional information and infographics. The actor registration module will be available to member states and economic operators from 1 December 2020.

- Infographic: Actor roles and SRN
- Infographic: Actor registration request process
- Infographic: Users access requests
- Video: Demo actor registration module

Templates of documents the actor registration request must include are also available:

- Declaration on information security responsibilities
- Mandate Summary document

The new section of the website additionally includes a user guide for economic operators and technical documentation on EUDAMED:

- Guide to using EUDAMED
- Actor Module Business Process – the M2M management will only be available when the UDI/Device module is made available
- Actor Module Business Rules
- AIM-Business Process – the first NB LAA will only be available when the certificate module is made available
- AIM-Business

4.2 New FAQ document on actor module published

The FAQ document on the actor module answers questions on seven identified topics:

- Countries available in EUDAMED from December 2020
- Actor registration process
- SRN
- Actor roles
- EUDAMED users
- Support
- Data Exchange

The document clarifies that until further notice, economic operators based in the UK, Switzerland and Turkey will not be able to submit applications in EUDAMED's actor registration module.

5 Notified body designation

5.1 17 notified bodies designated under the MDR, five under the IVDR

The EC has published an update to show the state of readiness of notified bodies in the designation process under the MDR and IVDR. So far, 17 notified bodies have been designated under the MDR and five under the IVDR. The figures show that the pandemic is stalling new designations, as joint assessment teams must pay site visits to the notified body applicants. The hold-ups can partly be explained with the current social distancing measures and travel restrictions that prevent on-site auditing.

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

- 3EC International a.s., Slovakia

The following additional NB with IVDR designation is listed in NANDO:
– TÜV Rheinland LGA Products GmbH, Germany

In all, 48 notified bodies have applied to the European Commission to be designated under the MDR and 15 under the IVDR.

6 Implementation activities on national levels

6.1 Netherlands: CCMO new competent authority for clinical investigations with medical devices

Since October 2020, manufacturers should notify the Central Committee on Research Involving Human Subjects (CCMO) of clinical investigations involving a medical device. The transfer of these tasks from IGJ to CCMO takes place in anticipation of the MDR.

6.2 Netherlands: Guidance on review of clinical investigations with medical devices according to MDR published

The CCMO published a guidance to set out the implications for the review of medical device research by the accredited Medical Research Ethics Committees (MRECs). The guidance focuses on the quality and safety of medical devices to be used in clinical investigations and on the new procedures for the submission, assessment and conduct of clinical investigation as a result of the MDR.

6.3 UK: MHRA issues new guidance on post-Brexit medical device regulations

The UK's MHRA issued a guidance outlining how medical devices will be regulated as of January 2021:

– The CE Mark as well as Conformity Assessment certificates issued by an EEA based notified body (under MDD/AIMD/MDR/IVDD/IVDR) will be recognised as a route to placing medical devices (both medical devices and in-vitro diagnostic medical devices) on the GB market until 30 June 2023.
– The UK Conformity Assessment Mark (UKCA), will be set up in parallel on 1 January 2021 as a new path to market for the UK.
– UKCA will be mandatory for placing a device on the UK market from 1 July 2023 onwards.

The guidance explains how the rules for placing medical devices on the Northern Ireland market (where the MDR and IVDR will apply from 26 May 2021 and 26 May 2022, respectively) will differ from those that will apply in the rest of the UK.

6.4 Switzerland: Swissmedic published an information sheet to answer frequently asked questions about Single Registration Numbers

The information sheet deals with the issuing of SRNs after the Art. 55 MedDO-2021 is put into operation (date to be determined by the Federal Council) by Swissmedic. The date from when SRNs can be requested will be announced as soon as possible. The information is based on the Medical Devices Ordinance (MedDO-2021) adopted by the Federal Council on 1 July 2020 and on the assumption that the existing Mutual Recognition Agreement will be updated.

7 IVD-specific issues

7.1 Medtech Europe reinstates call on EU institution to ensure transition to IVDR

With a recently published reflection paper, Medtech Europe raises awareness of devices that are currently self-declared under the IVD Directive and will become Class D under the IVDR. These devices are especially vulnerable to the IVDR transition period because they cannot benefit from the grace period. Of serious concern is the fact the conformity assessment infrastructure for Class D devices (including, for example, EU reference laboratories) is limited or missing altogether.

8 Miscellaneous

8.1 Team NB published analysis of survey on virtual audits

Team NB has carried out a survey on remote audits as they are becoming increasingly important due to the current pandemic situation. Based on the analysis of the survey, Team NB has published a position paper that underlines the usefulness of remote audits and states that they do not lead to results different from those of physical audits. In particular, the position paper highlights the positive outcome of the survey which states that the vast majority of remote audits, i.e. 75%, are considered successful. Furthermore, the paper argues that the remote verifications did not lead to less stable audits as there was no significant impact on the number of nonconformities found.

9 Sources

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