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

BCWG	Borderline & Classification Working Group
DKMA	Danish Medicines Agency
EC	European Commission
EMA	European Medicines Agency
EMDN	European Medical Device Nomenclature
GSPR	General Safety and Performance Requirements
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
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
SSCP	Safety and Clinical Performance Certificates and Summaries
UDI	Unique Device Identification
PECP	Performance Evaluation Consultation Procedure

3 European Commission issues proposal to extend IVDR's transition provisions

To smooth the transition from the current Directive 98/79/EC to the new Regulation (EU) 2017/746, to prevent disruption in the supply of essential in vitro diagnostic medical devices and to address the lack of capacity of notified bodies, the European Commission (EC) proposed a progressive roll-out of IVDR. The proposal includes additional transition periods for devices that need to undergo conformity assessment by Notified Bodies for the first time under the IVDR. The proposal distinguishes between risk classes and provides a transition period until May 2025 for high-risk devices (class D), until May 2026 for class C devices and until May 2027 for lower risk devices (class B devices and class A sterile devices). The Commission also proposes a deferred application of the requirements for devices manufactured and used within the same health institution (in-house devices).

Devices affected by the additional transitional periods can only benefit from them if they fulfil certain conditions. For example, they have to continue to comply with the Directive and there must be no substantial changes to their design and purpose. In addition, stricter rules on vigilance and market surveillance will also apply to products covered by the transitional periods.

The general date of application of the Regulation remains 26 May 2022. The IVDR will apply from 26 May 2022 to CE-marked in vitro diagnostic medical devices that do not require the intervention of a notified body (i.e. Class A non-sterile devices, which represent approximately 20% of the market). New in vitro diagnostic medical devices (i.e. those that do not have a manufacturer's certificate or declaration of conformity issued before 26 May 2022) are also subject to the IVDR as of 26 May 2022.

The proposal will now go to the European Parliament and Council for adoption.

4 Implementing and delegated acts & guidelines

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

The overview of the ongoing guidance documents the different MDCG subgroups are working on and the MDR and IVDR implementing measures rolling plan were updated in October 2021. According to this plan, the official announcement of the fully functional EUDAMED is expected for mid-2023.

4.2 MDCG guidance on the classification of medical devices under MDR issued

The MDCG issued the long-awaited guidance on the classification of medical devices under the MDR, providing a high-level overview of the regulations and graphical summaries. The guidance shows how the 22 rules in Chapter 3 of the MDR intersect with the four risk classes of medical devices and includes examples of the classification of specific devices.

4.3 MDCG guidance clarifies application of MDR requirements to legacy devices

Art. 120(3) of the MDR provides that specific devices certified under the prior Directives may, for a transitional period, continue to be placed on the market since the date of application of the MDR on 26 May 2021. MDCG 2021-25 outlines the requirements applicable to legacy devices, for example, regarding surveillance and vigilance.

4.4 MDCG issues Q&A on repackaging and relabelling activities under Article 16 of MDR/IVDR

In MDCG 2021-26, the rules for importers and distributors who repackage and relabel medical devices are explained, clarifying what activities would mean that the distributor or importer would need to assume manufacturer responsibilities.

4.5 Revision on guidance outlining NB requirements issued

The third revision of MDCG 2019-6 clarifies under what circumstances notified bodies can offer training to their manufacturer clients. For example, notified bodies are not allowed to provide pre-certification advice. Still, according to the updated guidance, the MDCG clarifies that training activities that are not client-specific and related to the regulation of devices or related standards are allowed.

4.6 MDCG document issued on Helsinki procedure under MDR/IVDR

In the so-called Helsinki procedure, decisions on borderline and classification issues are developed between the Member States at the European level and subsequently published in the Manual on Borderline and Classification. The system was revised by the Borderline & Classification Working Group (BCWG) of the MDCG

after the MDR came into force. In September 2021, MDCG published a document outlining the updated system agreed upon back in 2002 and was operational in the context of the Directives.

5 EUDAMED

5.1 Implementing decision on EUDAMED published

The MDR requires the EC to lay down the detailed arrangements for establishing and maintaining EUDAMED. Accordingly, the EC has adopted Implementing Regulation (EU) 2021/2078 of 26 November 2021 to provide these details such as applicable definitions, mode of access, nomenclature, technical and administrative support, ownership and processing of personal data, functioning rules, malfunction, and IT security.

5.2 Two additional EUDAMED modules available

The latest version of EUDAMED has been upgraded with two new modules: for UDI/device registration and on certificates and notified bodies. In addition, the EC has set up dedicated pages on the modules on its Medical Devices and EUDAMED website. However, the use of the NBs & Certificates module remains voluntary until EUDAMED is fully operational. Therefore, notified bodies can only register Safety and Clinical Performance Certificates and Summaries (SSCP) in EUDAMED if all parties mentioned in the certificates are registered. Parties to be registered include the manufacturer, authorised representative (if applicable) and/or the manufacturer of the system or procedure pack and the referenced base UDI-DI(s).

Now three modules are available for use on a voluntary basis; the actor registration section was launched in December 2020. Additional documents were updated in connection with the release of the modules, such as the ACTOR MODULE FAQs October v1.6, the EUDAMED user guide and an updated version of the EMDN nomenclature.

6 Notified body designation

6.1 25 notified bodies designated under the MDR, six under the IVDR

Twenty-five notified bodies are currently designated under the MDR and six under the IVDR.

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

- TüV Rheinland Italia SRL
- CERTIQUALITY S.r.l., Italy
- SGS Belgium NV

7 Implementation activities on national levels

7.1 Austria: New medical device act in force

The Austrian legislature enacted a new Medical Device Act 2021(3) (MDA 2021). The Act covers aspects of medical device law not included in the MDR or that the Member States have to determine in detail (for example, language requirements and advertising rules) and provides for implementation obligations and enabling provisions.

7.2 Denmark: Information on consultation procedure for medical devices containing medicinal substances

The Danish Medicines Agency (DKMA) has published information on the consultation procedure for medical devices containing medicinal substances, which includes a consultation with DKMA or another EU Competent Authority. On its Website, the DKMA outlines the process, provides an application form linked to the EMA guidance and informs about the costs of the consultation procedure.

7.3 Italy: Ministry of Health confirmed full applicability of existing restrictions on medical device advertising

The Italian Ministry of Health issued Circular 0081386. It confirmed that the national pre-authorisation requirements for advertising medical devices would continue to apply despite the application of the MDR, as it is compatible with and not repealed by Article 7 of the MDR. This only applies to devices not requiring a prescription or the assistance of a healthcare professional (Article 21 of Legislative Decree 46/97).

7.4 Finland: Medical device law implements national provisions

A new medical device law is in force in Finland, implementing the provisions set out in the MDR and IVDR that the Member States can define, such as the language requirements or the reprocessing of single-use devices.

7.5 Romania: New Ordinance no longer requires notification and database registration

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.

7.6 Turkey: Extension to update registration of Class I medical devices in Turkish database

Turkey's Ministry of Health extended the deadline for the update of registration of class I non-sterile/without measuring function medical devices until the end of 2021. Manufacturers and importers are required to register the EU Declaration of Conformity documents issued under the MDR and update the product registration. Otherwise, registrations of class I devices that are not updated will no longer be valid after 31 December 2021.

8 IVD-specific issues

8.1 MDCG publishes another update of joint implementation and preparedness plan for IVDR

The updated 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. The MDCG cites the implementation as a challenging task due to the lack of sufficient notified body capacity. However, the document does not mention the proposal to stagger implementation of final compliance IVDR deadlines according to the risk class of products (see Chapter 3).

8.2 Expert panels accept submissions for IVD performance evaluation consultation procedure and issue first opinion

In September 2021, the expert panel in the field of in vitro diagnostic medical devices informed that submissions from notified bodies for the Performance Evaluation Consultation Procedure (PECP) are accepted. It published its first opinion based on a manufacturer performance evaluation report submitted by a notified body in November 2021.

9 Miscellaneous

9.1 New requirements on medical devices that contain cobalt in force

The EU introduced new requirements on medical devices that contain cobalt in 2020, and the provisions of Commission Delegated Regulation (EU) 2020/2017 have been in force since 1 October 2021. The use of cobalt is not prohibited, but medical devices containing cobalt in a concentration greater than 0.1% weight by weight must meet the requirements established in Annex I, Chapter II, point 10.4 of the MDR.

9.2 EN ISO 13485 updated with annexes providing link to MDR's GSPR

EN ISO 13485:2016+A11:2021 has been issued, linking the specific clauses of the standard and the general safety and performance requirements (GSPR) of the MDR and IVDR.

9.3 Commission issues new recommendation on conformity assessment and market surveillance procedures in the context of COVID-19

On 2 September 2021, Commission Recommendation (EU) 2021/1433 on conformity assessment and market surveillance procedures in the context of the COVID-19 threat was published in the Official Journal of the European Union.

9.4 Team-NB issues position paper on MDR Article 117

Team-NB has published a position paper related to Article 117 of the MDR and issued a proposal for a notified body opinion template for cases a notified body opinion is required for the device part of a combination product.

9.5 Team-NB issues position paper on proposed AI regulation

In April 2021, the EC has presented a proposal for comprehensive regulations of artificial intelligence to address the risks associated with specific AI systems. Team-NB has issued a position paper about the EC's proposal to regulate AI applications to express its opinion and concerns regarding the forthcoming regulation. The main concerns focus on the interfaces and overlap between the AI Regulation and the MDR and IVDR.

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