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), MAY 2022

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

DMIDS	Medical Devices Information and Database System
EC	European Commission
EMA	European Medicines Agency
FPHC	French Public Health Code
IVDD	In Vitro Diagnostics Medical Devices Directive (98/79/EC)
IVDR	In Vitro Diagnostics Regulation (EU) 2017/746
JRC	Joint Research Centre
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation (EU) 2017/745
MRA	Mutual Recognition Agreement
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
SSCP	Summary of Safety and Clinical Performance
SSP	Summary of Safety and Performance
TİTCK	Turkish Pharmaceuticals and Medical Devices Authority
UDI	Unique Device Identification

3 The Date of Application of the IVDR has arrived

After a five years transition period, the date of application of the IVDR arrived on 26 May 2022. Announcing the application of the IVDR, the European Commission (EC) issued a press release outlining some of the introduced changes. As of the date of application of the IVDR, only seven notified bodies have been designated. Industry stakeholders keep voicing their concern about the lack of notified body capacity to handle the number of conformity assessments necessitated by the new regulation.

In another notice, the EC informed stakeholders that the mutual recognition and related trade facilitating effects for IVDs between the EU and Switzerland ceased to apply. Since the Mutual Recognition Agreement (MRA)

between Switzerland and the EU was not updated, Switzerland is treated as a third country from an EU perspective and vice versa.

4 Implementing and delegated acts & guidelines

4.1 Another update of the joint implementation and preparedness plan for IVDR issued

The joint implementation plan for the IVDR as well as the list of ongoing guidance documents issued by the MDCG were updated in April 2022.

4.2 Additional standards harmonised under MDR & IVDR

Currently, there are 16 harmonised standards listed for the MDR. After the first harmonised standards were published in the Official Journal in July 2021, additional nine standards were added in January 2022, and another two in May 2022. The Commission Implementing Decision (EU) 2022/757 of 11 May 2022 updates the list of standards harmonised under the MDR. With the Commission Implementing Decision (EU) 2022/729 of 11 May 2022, the EC has updated the list of standards harmonised under the IVDR.

4.3 Commission issues report to retain power to adopt delegated acts

The EC issued a report to retain its powers to adopt delegated acts. The MDR and IVDR empower the EC to adopt several delegated acts. Delegated acts supplement or amend basic laws, while implementing acts are intended to ensure uniform conditions for implementing these basic laws. Since the Medical Device and IVD Regulations were adopted in 2017, the five years to adopt delegated acts in the context of these regulations have ended. In the report, the EC concludes that it is necessary to extend this delegation of power for another five years.

4.4 MDCG issues questions and answers documents on UDI requirements under MDR & IVDR

With a new Q&A document, the MDCG has published further details on the application and implementation of UDI requirements under the MDR and IVDR.

4.5 MDCG updates guidance on summary of safety and clinical performance summary

MDCG 2019-9 of October 2019 aims to assist manufacturers in the preparation of the summary of safety and clinical performance (SSCP). In March 2022, the revised document was adopted. The changes in the revised version concern the following:

– Section 3: clarification of the link between the SSCP and the basic UDI-DI in EUDAMED;
– General requirements and templates: addition of a manufacturer reference number.

4.6 MDCG issues guidance on borderline products

MDCG 2022-5 provides explanations and examples to clarify the demarcation between the legal frameworks for medical devices and medicinal products. It also contains a general discussion and examples of borderline products. It includes a chapter dedicated to herbal products, substance-based devices, and medical device/medicinal product combinations.

4.7 MDCG guidance on interface between clinical trial regulation and IVDR issued

In a new MDCG document, questions about the interface of the IVDR and the Regulation (EU) No 536/2014 on clinical trials for medicinal products for human use were addressed. The guidance document aims to provide guidelines on topics such as the use of assays (including tests not meant to be developed into commercial products) and in-house IVDs without a CE mark in studies.

4.8 MDCG guidance on significant changes and IVDR's transitional provisions

MDCG 2022-6 outlines the conditions under which IVDs, which are compliant with the IVDD can remain on the market after the application date of the IVDR, provided that there are no significant changes in design and intended purpose.

4.9 MDCG issues guidance on IVDR requirements applicable to legacy devices

MDCG 2022-8 discusses how IVDR requirements apply to legacy devices and devices placed on the market before 26 May 2022 under the IVDD. IVDR requirements relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and devices are applicable since 26 May 2022.

4.10 MDCG issues summary of safety and performance template

MDCG 2022-9 provides a template for a summary of safety and performance (SSP) as required by the IVDR for manufacturers of class C and D devices (other than devices for performance studies). The SSP will be validated by a notified body (NB) and made available to the public via EUDAMED.

5 EUDAMED

5.1 Updated modules, user guides and technical documentation issued

At the beginning of April 2022, the European Commission released a new product version of the EUDAMED actors, UDI/devices registration and NBs & certificates modules. This version adds new functionalities, bug fixes and other improvements. Accordingly, the EC issued updated rules and guidance for the UDI/Devices module, and the notified bodies and certificates module. They also released an updated version of the existing user guide, which was first released for the launch of the actor registration module in 2020.

Actors

- ACTOR MODULE FAQs V 2.7
- EUDAMED: Economic Operator user guide V2.7

UDI/device registration

- UDI Devices - User guide V 2.7

Version 2.7 of the user guide has now been published. The document contains the definitions of the essential terms in the UDI field. It also describes a step-by-step for the procedure of registering a basic UDI-DI and a UDI-DI in EUDAMED. Additionally, the document describes how to manage product information and how to search for a product on the platform.

- EUDAMED UDI/Device data dictionary V2.7
- UDI Device Business rules v2.7
- UDI Device Enumerations v2.7
- DTX service definition for Economic Operators v2.7
- Economic Operators DTX notes v2.7
- Economic Operators - XML samples v2.7

NB & certificates

- Notified Bodies user guide – for the Production environment V2.7

This document contains the basic concepts and descriptions of the types and classes of certificates. It also describes a step-by-step of the procedure of registering an issued certificate, a rejected certificate and updating certificates in EUDAMED. In addition, the document contains guidance on SSCP management and how to search for a certificate on the platform.

- EUDAMED Certificates data dictionary v2.7
- EUDAMED Refused Certificate and Application data dictionary v2.7
- Certificate Business Rules v2.7
- Certificate Enumerations v2.7
- DTX Service Definition for Notified Bodies v2.7
- NBs - Data Exchange Notes - v2.7
- NB - XML samples v2.7

6 Notified body designation

6.1 29 notified bodies designated under the MDR, seven under the IVDR

Twenty-nine notified bodies are currently designated under the MDR and seven under the IVDR.

The following additional NBs with MDR designation are listed in NANDO:
- Slovenian Institute of Quality and Metrology (SIQ)
- TUV NORD Polska Sp. z o.o, Poland

The following additional NB with IVDR designation is listed in NANDO:
- 3EC International, Slovakia

In May 2022, the EC provided an update on the progress of notified body applications under the new regulations, outlining the different stages of the assessment process.

7 Implementation activities on national levels

7.1 Czech Republic: Modification of clinical trials module in national database

Modifications to the clinical trials module in the Czech medical device registry have been introduced. Different file numbers will be generated when requesting a change compared to the continuation of a clinical trial according to the changed procedure. A different file number will be used for the authorised trial than the subsequent requests.

7.2 Finland: Updated regulations applicable to IVDs compliant with Directive 98/78/EC

Fimea has updated the regulations that apply to IVDs, outlining the requirements on performance evaluation studies and reporting, conformity assessment of IVDs covered by the IVDD, and vigilance notification procedures.

7.3 Finland: New for clinical investigations according to the MDR clarified

On 15 March 2022, the Ordinance 01/2022 on clinical trials for medical devices came into force. It specifies the documentation to be submitted to Fimea for clinical trials conducted in Finland under Article 82 of the MDR. The Ordinance also clarifies the notification procedure for suspended or prematurely terminated investigations, and the report sponsors have to submit to Fimea within a year of the end of a clinical investigation.

7.4 France: New medical device ordinance adapts national medical device law

On 20 April 2022, a new ordinance adapting the French law to MDR was published to bring the French Public Health Code (FPHC) in line with the MDR. It outlines the specific provisions applicable to clinical investigations, the registration procedure for economic actors, and adopts the definition of accessories from the MDR. It also

identifies the National Agency for Safety of Medicines and Health Products (ANSM) as the competent authority and clarifies details on the market surveillance of Annex XVI products.

7.5 Germany: BfArM updates information on clinical investigations and performance evaluations

On its website, the BfArM updated its information on the requirements applicable in Germany until EUDAMED is fully functional. Applications and notifications for clinical trials must be submitted via the Medical Devices Information and Database System (DMIDS). This has been a requirement for MDs since the MDR's application date on 26 May 2021 and as of 26 May 2022, also for IVDs.

7.6 Poland: New medical device law in force

In April 2022, the Polish Medical Device Act was adopted to align the national legislation with the MDR and IVDR. Among other things, it defines the information obligations of economic operators on the market, the advertising rules, and the administrative penalties related to non-compliance with the MDR, the IVDR or the Act.

While the Act entered into force on 26 May 2022, some provisions will only be applicable later, such as the provisions on the advertising of medical devices (1 January 2023), and some of the provisions on the registration of devices and economic operators (1 July 2023).

7.7 Spain: New portal for registration of those responsible for placing medical devices on the market

The Spanish Agency for Medicines and Health Products (AEMPS) has launched a new portal to manage the registration of those responsible for placing health products on the market. The new portal went live on 15 February 2022 and replaced the previous system. However, data entered into the previous system remains valid as long as they are up to date.

7.8 Turkey: Draft medical device clinical trial regulation issued

The Turkish Pharmaceuticals and Medical Devices Authority (TİTCK) launched a public consultation on the draft of the *Medical Device Clinical Trials Regulation*. The draft aims to update the current regulation in accordance with the device regulation that was aligned with the MDR. It includes references to EUDAMED, details of submissions of all applications and notifications to the TİTCK, emergency security measures and the monitoring of post-marketing studies.

7.9 Turkey: Notice on EU-Turkey customs union agreement issued

On 13 April 2022, the European Commission published a notice to stakeholders on the EU-Turkey Customs Union Agreement in the field of medical devices. Turkey remains part of the internal market for medical devices under the MDR and IVDR. The Notice (re)confirms that Turkish legislation aligns with the MDR and IVDR and outlines the implications for authorised representatives and notified bodies.

8 Miscellaneous

8.1 Handover of experts panels secretariat to EMA

The EC has published a short statement informing about the transfer of the Commission's expert panels on medical devices and in vitro diagnostics from the Joint Research Centre (JRC) to the European Medicines Agency (EMA).

8.2 France's Snitem and Germany's BVMed ask to delay MDR implementation

The two largest EU national MedTech industry associations, France's Snitem and Germany's BVMed, have joined forces to call on the European Commission to delay the MDR compliance dates by at least two years.

In a jointly issued position paper, the industry associations argue that the MDR structure is not ready and more time is needed to create a fully functioning system. Snitem and BVMed add that the lack of necessary structures and obstacles companies are facing while proving the compliance of their products in a timely way, has catastrophic consequences on the availability of products.

The grace period gives eligible manufacturers an additional three years beyond the 26 May 2021 date of application to certify under the new MDR. The industry associations want to extend the grace period by two years for the highest risk class products (Class III and implantables) and four years for all other devices.

8.3 EC has adopted a proposal for a Directive on corporate sustainability due diligence

The new proposal provides for corporate due diligence to identify, prevent, mitigate, remedy and be accountable for negative impacts on human rights and the environment in a company's operations. The proposal is guided by the United Nations Guiding Principles on Business and Human Rights and the OECD Guidelines for Multinational Enterprises and Responsible Business Conduct, and internationally recognised human rights and labour standards.

9 Sources

Czech Republic, NISZP: Modification of the KZ module in RZPRO (22.02.2022).
European Commission: Update - Joint implementation and preparedness plan for Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) (01.04.2022).
European Commission: Ongoing guidance development and deliverables of MDCG Subgroups –April 2022* (April 2022).
European Commission: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (26.04.2022).
European Commission: OVERVIEW OF NBs AT EACH STAGE OF THE PROCESS (21.03.2022).
European Commission: NOTICE TO STAKEHOLDERS: EU-TURKEY CUSTOMS UNION AGREEMENT IN THE FIELD OF MEDICAL DEVICES (22.03.2022).
European Commission: Handover of Experts Panels Secretariat (02.03.2022).
European Commission: Just and sustainable economy: Commission lays down rules for companies to respect human rights and environment in global value chains (23.02.2022).
Finland, Fimea: Performance Evaluation Studies and Reporting of In Vitro Diagnostic Medical Devices (11.03.2022).
Finland, Fimea: Conformity assessment of in vitro diagnostic medical devices covered by EU Directive 98/79 / EC (Fimea, 11.03.2022).
Finland, Fimea: Vigilance Notification Procedures for the Manufacturer of In Vitro Diagnostic Medical Devices (Fimea, 11.03.2022).
Finland, finlex: 11.03.2022 Fimea / 2021/006212 (March 2022).
France, légifrance: Ordonnance n° 2022-582 du 20 avril 2022 portant adaptation du droit français au règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux (20.04.2022).
Germany, BfArM: Klinische Prüfungen und Leistungsbewertungsprüfungen (retrieved 08.04.2022).
Germany, BVMed: BVMed und SNITEM starten deutsch-französische Initiative zur MDR: „Wir müssen jetzt handeln!“ (14.03.2022).
Medical Device Coordination Group: MDCG 2022-10 - Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 (25.05.2022).

Medical Device Coordination Group: Update - MDCG 2019-9 - Rev.1 - Summary of safety and clinical performance (24.03.2022).
Medical Device Coordination Group: MDCG 2022 – 5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices (26.04.2022).
Medical Device Coordination Group: MDCG 2022-6 - Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR (04.05.2022).
Medical Device Coordination Group: MDCG 2022-8 Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC (20.05.2022).
Medical Device Coordination Group: MDCG 2022-9 Summary of safety and performance – Template (20.05.2022).
Medical Device Coordination Group: MDCG 2022-7 – Questions and Answers on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (20.05.2022).
Official Journal of the European Union: Commission Implementing Decision (EU) 2022/757 of 11 May 2022.
Official Journal of the European Union: Commission Implementing Decision (EU) 2022/729 of 11 May 2022.
Poland, ISAP: Act of 7 April 2022 on Medical Devices (07.04.2022).
Spain, AEMPS: The AEMPS launches a new RPS for the registration of those responsible for placing medical devices on the market (15.02.2022).
Turkey, TITCK.gov.tr: TIBBİ CİHAZ KLİNİK ARAŞTIRMALARI YÖNETMELİĞİ.