

IMPLEMENTATION OF THE NEW EU MEDICAL DEVICE REGULATIONS MDR (2017/745) AND IVDR (2017/746)

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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; 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

EC	European Commission
EMA	European Medicines Agency
IVDD	In Vitro Diagnostics 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

3 Procedure to adopt second MDR/IVDR corrigenda has started

The Council of the European Union published the second corrigenda to the [MDR](#) and [IVDR](#) on 25 November 2019. This started the 8-day silence procedure to adopt the corrigendum, requiring approval (no response implies approval) from all EU member-states before it is adopted by the European Parliament in order to take effect.

The most notable change of the MDR corrigendum is the proposed alteration to Article 120(3), as it would include certain class I devices into the four-year grace period that the MDR grants for devices certified under the Directives. This would benefit manufacturers of class I medical devices that need a notified body review for the first time under the MDR (mainly reusable surgical instruments, medical device software, and substance-based medical devices). The grace period applicable to legacy devices stipulates specific conditions: no significant changes in design and intended purpose and application of MDR requirements relating to postmarket surveillance, market surveillance, and vigilance.

The corrigendum shows minor other changes including changing the date until which devices placed on the market pursuant to the Directives can be made available or put into service in Article 120(4). The date has been advanced by one day to 26 May 2025. The corrigendum includes further edits, corrections and additions to Article 78(8), Article 84, Article 88(1), Article 120(8), Article 122, Annex I and Annex III.

The IVDR corrigendum introduces minor edits, corrections, and additions to Article 83(1), Article 110(8), Article 112, Article 113(3) point (a), Annex III and Annex VIII.

4 Implementing and delegated acts & guidelines

4.1 MDCG document outlines MDR & IVDR guidance development

The Medical Device Coordination Group (MDCG) has published a [document](#) outlining its plans for releasing 47 future guidance documents, indicating that most of the documents will be endorsed in the next few months.

4.2 Guidance on summary of safety and clinical performance (SSCP) published

The MDCG has published a guidance ([MDCG 2019-9](#)) on SSCP for manufacturers and notified bodies. According to Article 32 of the MDR, SSCPs are required for implantable devices and class III devices (other than custom-made or investigational devices).

4.3 Manufacturer incident report form updated

The [manufacturer incident reporting](#) form as well as related documents were revised and updated on the European Commission's website. Manufacturers have to report using the new MIR form as from January 2020:

- [New manufacturer incident report for importing](#) XML file with Adobe Professional
- [New manufacturer incident report XSD files](#) (for implementation in manufacturer' databases)
- [New manufacturer incident report help text](#)

4.4 Implementing decision on expert panel designation and call for expression of interest published

The EC published the [implementing decision 2019/1396](#) on how medical device expert panels will be designated under the MDR. The EC published a call for expression of interest for expert panels, several forms, declarations and guidances as well as granting an extension of two weeks to the initially communicated deadline, until 24 November 2019.

4.5 MDCG document clarifies application of transitional provisions concerning MDD certificates

Document [MDCG 2019-10](#) clarifies the special conditions that certificates issued in accordance with the MDD, and the related devices thereof, have to comply with in order to remain valid until May 2024 at the latest. The document outlines the continuing responsibilities of national competent authorities and notified bodies in relation to overseeing products that make use of the grace period.

4.6 Guidance on qualification and classification of Medical Device Software

The MDCG has issued a guidance document ([MDCG 2019-11](#)) to help qualify software falling within the scope of the MDR or IVDR as Medical Device Software (MDSW). The document provides guidance on the application of classification criteria and includes information related to placing on the market.

4.7 Draft proposes changes to common technical specifications for IVDs

A [draft](#) commission implementing decision was published to update the common technical specifications for certain in vitro diagnostic medical devices. The draft proposes to update:

- the state-of-the-art status
- the definitions of first line and confirmatory assays
- the requirements for self-tests
- the requirements for human immunodeficiency virus (HIV) and Hepatitis C rapid tests and confirmatory assays

The updated specifications aim to reinforce the control of notified bodies over the placing of IVDs on the market.

4.8 Updated version of Q&A document on notified bodies requirements

The second version of [MDCG 2019-6](#) clarifies inter alia that a notified body needs to make clear in its communication to the manufacturer what is considered as substantial changes to the QMS or the covered device-range. NBs must have documented procedures defining how different changes need to be notified and assessed prior to their implementation; and how the assessment will be documented (in particular, when the approval of such a change will take the form of a supplement to the previously issued certificate).

4.9 EMA updates Q&A document on MDR implementation

The European Medicines Agency (EMA) has updated a [Q&A document](#) on the implementation of the MDR. The newly added questions examine aspects relating to the applicability of the requirements of the MDR to medicinal products with an integral or co-packaged medical device.

4.10 Final SCHEER guidelines published

The Scientific Committee on Health and Environmental Risks (SCHEER) published the [final version](#) of its guidelines on benefit-risk assessment (BRA) of phthalates in certain medical devices.

5 Eudamed

End of October 2019, the European Commission [officially confirmed](#) the delay in the preparation of the Eudamed database, explaining that it would be operational once the entire system and its different modules had achieved full functionality and had been subject to an independent audit. The launch has been delayed for two years and will be done together for medical and in-vitro medical devices in May 2022.

Registration and vigilance requirements already applicable under the Directives will continue to apply to exchange of information regarding vigilance reporting, clinical investigations, registration of devices as well as economic operators, and certificate notifications.

6 Notified body designation

6.1 Seven NBs designated under the MDR, two under the IVDR

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)

German notified body, DEKRA, has been designated as the first notified body under the IVD Regulation. BSI UK is the second notified body to be designated under the IVD Regulation. BSI stated that they had received designation for the full scope, covering all devices for IVDR.

6.2 Updated joint assessments progress report

The updated [document](#) reports the following numbers beginning October 2019:

- 40 live applications for designation have been received by the European Commission against the MDR, 11 against the IVDR

- Nine MDCG recommendations have been made
- Nine applications have reached the final opinion stage of joint assessment

6.3 First devices under MDR certified

BSI UK and TÜV SÜD have certified the first products under the MDR:

- BSI UK has certified Novartis' Concept1 inhaler
- TÜV SÜD has certified Biotronik's Renamic programmer software

7 Implementation activities on national levels

7.1 Denmark: Regulators seek to help smaller companies with MDR compliance

The Danish Medicines Agency (DKMA) has started a [pilot project](#) to support start-ups and small-to-medium-sized manufacturers (based anywhere in the world) to comply with the MDR. The pilot project will offer guidance on the new regulatory requirements until the end of 2019 (with a possible continuation of the project). It includes one-on-one meetings with a board and counselling is provided.

7.2 Germany: Medizinprodukte-Anpassungsgesetz-EU adopted

On 6 November 2019, the Federal Cabinet adopted a draft law to adapt the German medical devices legislation (Medizinproduktegesetz MPG) to regulation of MDR and IVDR (Medizinprodukte-Anpassungsgesetz-EU MPAnpG-EU).

7.3 UK: Medical device regulatory system proposed for no-deal scenario

The UK's exit from the EU has been delayed again, this time until end of January 2020. UK's MHRA informed in February 2019 that the UK would have its own medical device regulatory system, which would come into force once the UK left the EU without a deal. [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(UK MDR 2019\)](#) will transpose all key elements of the MDR and IVDR as well as the transitional timelines for the full application of those two regulations.

In September 2019, the [section](#) describing the requirement of a UK responsible person was added, clarifying that the said person must be physically located in the UK.

7.4 Switzerland: Regulation of combination products will be aligned to MDR

Swissmedic [stated](#) that the authorisation requirements for integral combination products would be adapted to the provisions of the European MDR. Manufacturers of integral combination products without a CE certification mark must demonstrate that the medical device component satisfies the applicable basic safety and performance requirements of Annex I of the MDR.

8 Miscellaneous

8.1 Oversight of medical devices sector passes back to DG Santé

The oversight of the medical devices sector will pass from the European Commission's Directorate General Grow back to DG Santé. The announcement concerning the [allocation of portfolios and supporting services 2019 – 2024](#) indicates that devices and pharma are both to move in parallel, but there is no indication whether they will be placed within the same, or within different units under DG Santé.

9 Sources

Council of the European Union: [Corrigendum to Regulation \(EU\) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation \(EC\) No 178/2002 and Regulation \(EC\) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC](#) (Official Journal of the European Union L 117 of 5 May 2017).

Council of the European Union: [Corrigendum to Regulation \(EU\) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU](#) (Official Journal of the European Union L 117 of 5 May 2017).

Danish Medicines Agency: [Nyt koncept for vejledning om reglerne om medicinsk udstyr](#) (15.08.2019).

European Commission: [Allocation of portfolios and supporting devices](#) (07.11.2019).

European Commission: [Commission Implementing Decision \(EU\) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation \(EU\) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices \(Text with EEA relevance.\)](#) (11.09.2019).

European Commission: [Draft Commission Implementing Decision amending Decision 2002/364/EC as regards definitions of first-line assays and confirmatory assays, requirements for devices for self-testing and requirements for HIV and HCV rapid tests, confirmatory and supplementary assays.](#)

European Commission: [European database on medical devices \(EUDAMED\).](#)

European Commission: [Joint Assessments – Progress Report Update](#) (02.10.2019).

European Commission: [Manufacturer incident report form 2020](#) (30.09.2019).

European Commission: [Nando \(New Approach Notified and Designated Organisations\) Information System.](#)

European Commission: [New manufacturer incident report for importing XML file with Adobe Professional](#) (30.09.2019).

European Commission: [New manufacturer incident report XSD files](#) (for implementation in manufacturer' databases)

European Commission: [New manufacturer incident report help text](#) (30.09.2019).

European Commission: [Transition Timeline from the Directives to the Regulations](#) (12.04.2019).

European Commission, Scientific Committee on Health, Environmental and Emerging Risks (SCHEER): [Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction \(CMR\) or have endocrine-disrupting properties \(ED\)](#) (18.06.2019).

European Commission, Medical Device Coordination Group: [MDCG 2019-6 v2 Questions and answers: Requirements relating to notified bodies](#) (17.10.2019).

European Commission, Medical Device Coordination Group: [MDCG 2019-9 Summary of safety and clinical performance A guide for manufacturers and notified bodies](#) (26.09.2019).

European Commission, Medical Device Coordination Group: [MDCG 2019-10 Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC](#) (04.10.2019).

European Commission, Medical Device Coordination Group: [MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation \(EU\) 2017/745 – MDR and Regulation \(EU\) 2017/746 – IVDR](#) (11.10.2019).

European Commission, Medical Device Coordination Group: [Ongoing Guidance development within MDCG subgroups – October 2019](#) (31.10.2019).

European Medicines Agency: [Questions & Answers on Implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations \(\(EU\) 2017/745 and \(EU\) 2017/746\)](#) (21.10.2019, Rev. 1).

Legislation.gov.uk: [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#)

Medicines and Healthcare products Regulatory Agency: [Regulating medical devices in the event of a no-deal Brexit](#) (last updated 09.10.2019).

Swissmedic: [Revised requirements regarding combination products](#) (05.11.2019).