Newsletter | September 2023

For more information and regular updates please consult our website HERE.

As we continue our efforts to support the implementation of the **Medical Devices Regulation (EU) 2017/745 (MDR) and In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR)**, we aim to keep you informed about the latest developments, and all relevant news and events.

In this edition of our newsletter, we bring you updates on the September 2023 session in Berlin of the International Medical Device Regulators Forum (IMDRF) chaired by the EU, new initiatives and publications, and much more!

In this issue:

EU 2023 Chair of the Management Committee of the International Medical Device Regulators Forum (IMDRF) – New session in Berlin, Germany

Under the EU 2023 Chair of the Management Committee of the International Medical Device Regulators Forum (IMDRF), after the session in Brussels, Belgium on 27-28 March 2023, there will be a new session in Berlin, Germany on 25-26 September 2023:

- Day 1 - 25 September 2023 - Joint IMDRF / Stakeholder (DITTA-GMTA) Workshop - Specialised Regulatory Pathways
- Day 2 - 26 September 2023 - IMDRF Stakeholder Forum

For more, see "EU chairs IMDRF in 2023" from the Commission's webpage on International Cooperation, particularly the webpage IMDRF 2023 EU Chair.

First Stakeholder Consultation Workshop for the "Study on Regulatory Governance and Innovation in the field of Medical Devices"

The First Stakeholder Consultation Workshop will take place on 21 September 2023 in Brussels' EY office (Diegem) and online.

transitional provision under Article 120 of the MDR
- Meetings of the Medical Device Coordination Group (MDCG)
- New Commission Delegated Regulation on the assignment of Unique Device Identifiers for contact lenses
- New Commission Implementing Regulation (EU) 2023/1194 on transitional provisions for products without an intended medical purpose (Annex XVI MDR)
- New publications of lists of references of harmonised standards in support of the MDR and IVDR
- Updated MDR/IVDR notified bodies survey on certifications and applications (survey results with data status 31 March 2023)
- Updated information on the applications for designation as a notified body under the MDR and the IVDR
- New section on the Notified Body Coordination Group - NBCG-Med
- Update on the coverage of scopes for the upcoming designation of EURLs
- Ongoing consultations under the Performance Evaluation Consultation Procedure (PECP)
- Advice on the influenza virus on request from the Medical Device Coordination Group

For more, see the information and link to register for participation.

Updated Q&A document on practical aspects related to the implementation of Regulation (EU) 2023/607 and templates for notified body confirmation letter and for manufacturer's declaration

After the adoption of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) for the temporary provisions for certain medical devices and *in vitro* diagnostic medical devices, the European Commission issued a Q&A document on practical aspects of implementation of the amending Regulation. An update (Rev. 1) of the Q&A document is now available, as well as a template for notified body confirmation letter endorsed by NBCG-Med, and a manufacturer's declaration available on the websites of EU-level industry associations.

For more, see the Commission's webpages on Extension of the transition periods provided for in the regulations and on Guidance.

Flowchart to assist in deciding whether or not a device is covered by the extended MDR transitional period

The European Commission published a Flowchart - Conditions and deadlines for placing 'legacy devices' and class III custom-made implantable devices on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607 to help decide ifa device is covered by the extended transitional period for Regulation (EU) 2017/745 on MDR.

For more, see the Commission's webpage on Extension of the transition periods provided for in the regulations.

Updated factsheet for authorities in non-EU/EEA countries

The European Commission updated the Factsheet for authorities in non-EU/EEA states on medical devices and *in vitro* diagnostic medical devices, to outline changes introduced by Regulation (EU) 2023/607 temporary provisions for certain medical devices and *in vitro* diagnostic medical devices.

For more, see the Commission's webpages on Extension of the transition periods provided for in the regulations and on Publications.

Addendum 1 to MDCG 2022-18 Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

The Medical Device Coordination Group (MDCG) endorsed MDCG 2022-18 - Addendum 1, recommending that, after Regulation (EU) 2023/607 comes into force, national competent authorities limit the application of Article 97 of Regulation (EU) 2017/745 (MDR) in accordance with MDCG 2022-18 to exceptional circumstances.

For more, see the Commission's webpage on Guidance.

Revision of MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR

The MDCG endorsed MDCG 2020-3 Rev.1 as guidance on significant changes on the transitional provision under Article 120 of the MDR for devices covered by certificates according to MDD or AIMDD, in alignment with Regulation (EU) 2023/607 and guidance MDCG 2022-2.

For more, see the Commission's webpage on Guidance.

Meetings of the Medical Device Coordination Group (MDCG)

On 6-7 June 2023, the MDCG met with national competent authorities. On the agenda, the state of play of transition to the MDR and the IVDR, the EU4Health actions supporting the implementation of the Regulations, and other issues for information and discussion. On 7 June, a specific Workshop on the update of the Q&A document on the practical implementation of the extension of the MDR transitional period took place.

For more, see the information on the 6-7 June 2023 MDCG meeting from the Register of Commission Expert Groups and Other Similar Entities.
The next meeting of the MDCG is scheduled for 10-11 October 2023.

The 2023 MDCG and MDCG subgroups meetings planning is available from the Commission's webpage on Medical Device Coordination Group Working Groups.

New Commission Delegated Regulation on the assignment of Unique Device Identifiers for contact lenses

The European Commission adopted Commission Delegated Regulation of 10.7.2023 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for contact lenses.

As the text of the MDR is to be amended, it is currently under scrutiny by the European Parliament and the Council for three months, as in the Register of delegated and implementing acts. If no comments are raised, the act will be published in the *Official Journal of the European Union* (OJEU) to become applicable in two years.

New Commission Implementing Regulation (EU) 2023/1194 on transitional provisions for products without an intended medical purpose (Annex XVI MDR)

The European Commission adopted Commission Implementing Regulation (EU) 2023/1194 of 20 June 2023 amending Implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain products without an intended medical

purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council, to adapt the temporary provisions of Implementing Regulation (EU) 2022/2346 to the transitional period for certain medical devices as extended by Regulation (EU) 2023/607.

On 22 June 2023, Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices has come into force. Subject to the amended transitional provisions laid down in Commission Implementing Regulation (EU) 2022/2346, the MDR therefore now applies to Annex XVI products.

For more, see the Commission's webpage on Manufacturers of devices without an intended medical purpose.

New publications of lists of references of harmonised standards in support of the MDR and IVDR

The European Commission published Commission Implementing Decision (EU) 2023/1410 of 4 July 2023 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for sterilization of health care products and biological evaluation of medical devices and Commission Implementing Decision (EU) 2023/1411 of 4 July 2023 amending Implementing Decision (EU) 2021/1195 as regards a harmonised standard for sterilization of health care products, to add new references of harmonised standards in support of the MDR and the IVDR respectively.

For more, see the Commission's webpage on Harmonised standards.

Updated MDR/IVDR notified bodies survey on certifications and applications (survey results with data status 31 March 2023)

The European Commission published an updated document with the Notified bodies survey results on certifications and applications under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR), with data status of 31 March 2023.

For more, see the Commission's webpage on Notified Bodies.

Updated information on the applications for designation as a notified body under the MDR and the IVDR

The European Commission published updated information on the applications for designation as a notified body under Regulations (EU) 2017/745 onMDRs and 2017/746 on IVDRs as an Overview at each stage of the process.

For more, see the Commission's webpage on Notified Bodies.

New section on the Notified Body Coordination Group - NBCG-Med

The European Commission set up a new section in the website on medical devices devoted to the Notified Body Coordination Group - NBCG-Med. Its activities and documents produced are outlined.

For more, see the Commission's webpage on Dialogue between interested parties.

Update on the coverage of scopes for the upcoming designation of EURLs

The European Commission published an update on the call for applications 2022-2023 regarding the upcoming designation of EU reference laboratories (EURLs) for high-risk *in vitro* diagnostic medical devices (IVDs).

For more, see the Commission's webpage on In Vitro Diagnostics - EU reference laboratories (EURLs).

Ongoing consultations under the Performance Evaluation Consultation Procedure (PECP)

Two consultations under the Performance Evaluation Consultation Procedure (PECP) are currently ongoing for the *in vitro* diagnostics expert panel under Regulation (EU) 2017/746 on IVDRs.

For more, see the Commission's webpage on Expert Panels.

Advice on the influenza virus on request from the Medical Device Coordination Group

The IVD Expert Panel/Influenza Sub-group provided Advice on the influenza virus as requested by the MDCG.

For more, see the Commission's webpage on Expert Panels.

Stay tuned for future updates!

To stay up to date on all information related to medical devices and *in vitro* medical devices, please visit the Medical Devices section on the Commission's Public Health website regularly.

Register to the stakeholder's database here to stay up to date and receive the quarterly newsletter.

Your opinion matters to us! We are launching a survey to better understand what information you need regarding the EU Regulations on MDRs and IVDRs. Particularly, how the changes in the legislation are affecting stakeholders directly involved and what challenges the stakeholders are facing to ensure a smooth transition to the new regulations. Take part in the survey here.

For more information and regular updates please consult our webpages

- **Public health - Medical Devices:** https://health.ec.europa.eu/medical-devices-sector_en
- **Overview on the new Regulations including factsheets and communication material:** https://health.ec.europa.eu/medical-devices-new-regulations/overview_en
- **Publications and factsheets:** https://health.ec.europa.eu/medical-devices-sector/publications_en
- **Getting ready for the new Regulations:** https://health.ec.europa.eu/medical-devices-new-regulations/getting-ready-new-regulations_en
- **New Regulations including legal texts, implementing measures and delegated acts:** https://health.ec.europa.eu/medical-devices-sector/new-regulations_en
- **Guidance documents:** https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
- ***In Vitro* Diagnostics:** https://health.ec.europa.eu/vitro-diagnostics_en
- **Topics of interest including counterfeiting, custom-made devices, financing, in-house medical devices, software and apps:** https://health.ec.europa.eu/medical-devices-topics-interest/overview_en
- **Harmonised standards:** https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en
- **Notified bodies:** https://health.ec.europa.eu/medical-devices-topics-interest/notified-bodies_en

- **Unique device identifier (UDI):** https://health.ec.europa.eu/medical-devices-topics-interest/unique-device-identifier-udi_en
- **EU UDI Helpdesk:** https://webgate.ec.europa.eu/udi-helpdesk
- **Reprocessing:** https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices_en
- **Manufacturers of devices without an intended medical purpose:** https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices/manufacturers-devices-without-intended-medical-purpose_en
- **Dialogue between interested parties:** https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties_en
- **Medical Device Coordination Group (MDCG) and subgroups/working groups:** https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/overview_en, https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en
- **Medical Device Coordination Group (MDCG) in the Register of Commission Expert Groups and Other Similar Entities:** https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&do=groupDetail.groupDetail&groupID=3565
- **International Cooperation:** https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/international-cooperation_en
- **Expert panels:** https://health.ec.europa.eu/medical-devices-expert-panels_en
- **Eudamed:** https://health.ec.europa.eu/medical-devices-eudamed_en
- **Eudamed database:** https://ec.europa.eu/tools/eudamed/
- **Eudamed Information Centre:** https://webgate.ec.europa.eu/eudamed-help/
- **EuropeanMedical Device Nomenclature (EMDN):** https://webgate.ec.europa.eu/dyna2/emdn/A