MEDICAL DEVICES News

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Medical devices and ***in vitro*** diagnostic medical devices (IVDs) play a vital role in saving lives by providing solutions for the prevention, diagnosis, monitoring and treatment of disease. With over 500 000 types of medical device and IVD – ranging from sticking plasters to X-ray machines – on its market, the EU has a competitive and innovative medical device sector, characterised by many small and medium-sized enterprises.

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Webinar for patients

The EU medical device sector is supported by a new regulatory framework that aims to protect patients' health by ensuring safe and performant medical devices and at the same time to support innovation. The new framework consists of two new regulations – Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on IVDs (IVDR).

The MDR became applicable on 26 May 2021. A webinar for patients was held on 7 May 2021 to spread knowledge and information on the main aspects of the new Regulation.

To view information about the webinar and listen to the proceedings, click here.

UDI Helpdesk launched

Introduced under the MDR and IVDR, the new helpdesk for the EU's Unique Device Identification System (UDI Helpdesk) was launched in May 2021. The UDI Helpdesk helps economic operators to meet their obligations under the new Unique Device Identification system. It also provides support with use of the European Medical Device Nomenclature, which the European Commission has made available to manufacturers and other natural or legal persons who are required by the MDR and IVDR to use it.

To reach the UDI Helpdesk click here.

Transitional provisions for IVD certification

devices
- Harmonised standards for the MDR and IVDR: standardisation request and first publications in the OJEU
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- *In vitro* diagnostic medical device panel

The IVDR becomes applicable on 26 May 2022. It stipulates that as part of their conformity assessment, certain elements of class D IVDs must be reviewed by an expert panel. The IVDR also includes provisions on the designation of EU reference laboratory (EURL) which may be involved in the testing of certain IVDs. In April 2021, the Medical Device Coordination Group (MDCG) endorsed MDCG 2021-4, a document with guidance on how to apply the provisions of the IVDR related to expert panels and EURLs before its entry into application.

To read the MDCG 2021-4 document, click here.

Questions & Answers for applicants for and holders of marketing authorisations for medicinal products and notified bodies

The updated Q&A document elaborated by the European Medicines Agency (EMA) together with national competent authorities and the European Commission provides practical considerations concerning the implementation of the MDR and the IVDR for specific combinations of medicinal products and medical devices.

To read the Q&A, click here.

Rules for registration in EUDAMED

The creation of EUDAMED, the European database on medical devices, is a key aspect of the MDR and IVDR. EUDAMED will contain a living picture of the lifecycle of all medical devices available on the EU market and a large part of the information will be made publicly available. In July 2021 the MDCG endorsed the MDCG 2021-13 document, a Q&A giving guidance on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 of the MDR and Article 28 of the IVDR.

For the full MDCG 2021-13 Q&A, click here.

Instructions for generating identification numbers for clinical investigations

In carrying out clinical investigations under the MDR, competent authorities use the Eudamed2 databank to obtain a single identification number (CIV-ID). In July 2021, the MDCG endorsed the MDCG 2021-20 guidance document that provides instructions for generating CIV-IDs for MDR clinical investigations.

To read MDCG 2021-20, click here.

Explanatory notes on IVDR codes

Codes established by Commission Implementing Regulation 2017/2185 are used by designating authorities to define a notified body's scope of designation. They are also used by the notified bodies to describe the individual qualifications of staff members, as

well as the qualifications required for assessing a device. MDCG 2021-14 explains the different levels of the codes and how they should be used, including as regards the establishment of conditions for ensuring their harmonised use, especially when allocating resources for conformity assessment activities.

To read MDCG 2021-14, click here.

Application forms and applied-for scope forms for designation as notified bodies

In July 2021 the MDCG endorsed the application forms to be submitted by conformity assessment bodies in order to be designated as notified bodies under the MDR (MDCG 2021-15) and IVDR (MDCG 2021-16), along with forms related to the scope of each application as regards product types and assessment activities (MDCG 2021-17 and MDCG 2021-18).

To view the documents, click here.

Easier identification for safer medical devices

The Unique Device Identification (UDI) system facilitates identification and traceability of medical devices, improves surveillance and incident reporting and supports corrective actions, all of which enhances the effectiveness of post-market safety activities. In July 2021 the MDCG endorsed MDCG 2021-19, a guidance note to help organisations to integrate the UDI system into their own quality management systems.

For the text of the MDCG 2021-19 guidance, click here.

Harmonised standards for the MDR and IVDR: standardisation request and first publications in the OJEU

The European Commission adopted the standardisation request in support of the MDR and IVDR on 14 April 2021. It was accepted by the European standardisation organisations, CEN and Cenelec on 12 May, becoming fully applicable following the provision of a joint work programme on 28 May. On that basis, the first references to harmonised European standards were published in the Official Journal of the European Union (OJEU) on 19 July for the MDR and on 20 July for the IVDR. The voluntary use of these harmonised standards confers a presumption of conformity with the requirements of the regulations they aim to cover. Depending on submissions from CEN and Cenelec, more references will be published by the Commission in the coming months.

The standardisation request is available here. The first publications in the OJEU of references to harmonised standards are available here (MDR) and here (IVDR). To read more about harmonised European standards for medical devices, click here (topics of interest) and here (MDCG 2021-5 – guidance).

Evaluating performance of SARS-CoV-2 IVDs

MDCG 2021-21 published in August 2021 provides guidance on the performance evaluation of SARS-CoV-2 IVDs in the context of conformity assessment under either Directive 98/79/EC on IVDs or the IVDR. The guidance is addressed to all interested parties and should form the basis for the adoption of common specifications for IVDs.

To read the MDCG 2021-21 guidance, click here.

Clarification on 'first certification for that type

of device' and corresponding procedures

For class D devices, Article 48(6) of the IVDR establishes conditions to be applied by notified bodies in order to determine whether they have to consult an expert panel regarding the performance evaluation report of the manufacturer. These conditions are that there is an absence of common specifications for the device in question and that the certification being applied for is the first for that type of device. Endorsed in August 2021, MDCG 2021-22 provides clarification on these conditions and the procedures to be followed by notified bodies in consulting the expert panel.

To read MDCG 2021-22, click here.

Guidance on certification activities for notified bodies, distributors and importers

Article 16(4) of both the MDR and IVDR provides for the designation of notified bodies to certify that the quality management systems of distributors and importers of devices comply with the requirements laid down in the two regulations. To provide guidance on this matter, the MDCG endorsed the MDCG 2021-23 guidance document in August 2021. It mainly focuses on the activities of notified bodies but also gives clarifications regarding the quality management systems they are expected to assess.

To read the MDCG 2021-23 document, click here.

In vitro diagnostic medical device panel

Expert panels are crucial sources of valuable scientific input for the implementation of the MDR and IVDR. As a notified body, you can hand in your submissions for the Performance Evaluation Consultation Procedure to the IVD panel from 3 September 2021.

For more information on expert panels, click here.

For more information and regular updates please consult our websites

- **Public health – Medical devices:** ec.europa.eu/health/md_sector/overview;
- **New regulations including dedicated factsheets:** ec.europa.eu/health/md_newregulations/overview;
- **Getting ready:** ec.europa.eu/health/md_newregulations/getting_ready, **including guidance documents:** ec.europa.eu/health/md_sector/new_regulations/guidance;
- **MDCG and MDCG subgroups:** ec.europa.eu/health/md_dialogue/overview, ec.europa.eu/health/md_dialogue/mdcg_working_groups;
- **Expert panels:** ec.europa.eu/health/md_expertpanels/overview;
- **EUDAMED:** ec.europa.eu/health/md_eudamed/overview;
- **Factsheets on new regulations for manufacturers of medical devices, manufacturers of IVDs, authorised representatives/importers/distributors, competent authorities in non-EU/EEA countries, healthcare professionals and health institutions, and for the procurement ecosystem:** ec.europa.eu/health/md_newregulations/publications;
- **EU UDI Helpdesk:** eu-udi.zendesk.com/hc/en-150.

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