MEDICAL DEVICES News

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

As intensive preparations continue for the full roll-out of the new medical devices Regulation (MDR) and in vitro diagnostic medical devices Regulation (IVDR), we strive to keep you up to date on all relevant news and events. In this issue of our newsletter we update you on the roll-out of the IVDR and point you to guidelines on the classification of medical devices, among other news.

In this issue

Commission proposes a progressive roll-out of IVDR

On 14 October 2021, the Commission made a proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 – IVDR- as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices (COM(2021)627 final). The aim of the proposed Regulation, which needs to be adopted by the European Parliament and the Council, is to smooth the transition from the current Directive 98/79/EC to the new Regulation (EU) 2017/746 in order to prevent disruption in the supply of essential in vitro diagnostic medical devices. See also a press release and Q&A. The new Regulation proposal does not change the date of application of IVDR which remains the same, i.e. 26 May 2022.

Read all about the progressive roll-out of IVDR here. Check the Q&A section and the full overview of the new regulations on medical devices for further information.

EUDAMED - UDI/Devices and NBs & Certificates modules now open

The EUDAMED module on UDI/device registration and the module on Notified Bodies and Certificates are open, so economic operators and notified bodies can start entering data in EUDAMED on a voluntary basis.

See here for more information.

MDCG issues guidance on classification of medical devices

The Medical Device Coordination Group (MDCG) has issued MDCG 2021-24, a set of guidelines on the classification of medical devices, with information on the purpose and practical relevance of classification, how to carry out classification and the application of classification rules. The guidelines also contain a general explanation of the rules and of practical issues that arise, along with more in-depth explanations of individual rules.

To read the MDCG 2021-24 document, click here.

Helsinki Procedure for borderline and classification under MDR/IVDR

An updated version has been made available of the system agreed at the Medical Device Competent Authorities Meeting in Helsinki (Helsinki Procedure) in October 2002. The purpose of the system is to allow consultation among competent authorities on borderline and classification issues concerning medical devices and to ensure that the agreements are reflected in the Manual on Borderline and Classification for Medical Devices.

To read the document, click here.

MDCG issues report on transitional provisions

The Medical Device Coordination Group (MDCG) ad hoc task-force on transitional provisions ('legacy devices' and devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC) has issued the MDCG 2021-25 report, which has been endorsed as an MDCG guidance.

To read the MDCG 2021-25 document, click here.

Q&A on re-packaging and re-labelling activities

The Medical Device Coordination Group (MDCG) has issued MDCG 2021-26 - a set of questions and answers about re-packaging and re-labelling obligations introduced by Article 16(2) to (4) under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR).

To read the MDCG 2021-26 document, click here.

Factsheets – more language versions to be published soon

To support as many stakeholders as possible along the medical device supply chain, both in the European Union and globally, we will be publishing new editions of our factsheets in other languages soon.

Make sure to check the publications section on Medical Devices portal regularly to stay up to date on new resources as they become available.

Stay tuned for future updates!

To stay up to date on all information related to medical devices and in vitro medical devices within the context of the new Regulations make sure to visit the Medical Devices section on the Commission website regularly.

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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