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Client Newsletter
Medical Device Regulatory Updates

MDCG 2021-25 Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC.

Through this guidance the MDCG clarifies that the MDR's post-market surveillance, market surveillance, and vigilance requirements apply to legacy devices.

The guidance also specifically addresses the application of Article 86 MDR on the periodic safety update report (PSUR), and states that manufacturers of "legacy devices" are subject to the requirement to draw up and update PSURs in accordance with the aforementioned MDR Article.

In addition, also other MDR requirements should apply to "legacy devices", provided that those requirements relate to post-market surveillance, market surveillance, vigilance, registration of economic operators and devices.

The MDCG 2021-25 can be found here.

MDCG 2021-26 Q&A on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

The questions and answers covered by this document aim to guide economic operators carrying out any of the activities mentioned in points (a) and (b) of Article 16(2) of the MDR/IVDR concerning relabelling and repackaging of devices. It is noted that Article 16(2), (3) and (4) of the MDR/IVDR do not apply to operators subcontracted by the manufacturer (that may also qualify as importers or distributors), who also carry out relabelling and/or repackaging activities on behalf and under the control of the manufacturer.

The MDCG 2021-26 can be found here.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2226 of 14 December 2021 laying down rules for MDR as regards electronic instructions for use of medical devices

For some medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial. It can reduce the environmental burden and reduce costs for the medical device industry while maintaining or improving the level of safety.

The European Commission has published Implementing Regulation (EU) 2021/2226, laying down rules for the application of Regulation (EU) 2017/745 as regards electronic instructions for use (eIFUs) of medical devices. This regulation entered into force on the January 3, 2022.

This Implementing Regulation establishes the conditions under which information in the instructions for use, as defined by Article 2(14) of the MDR and detailed in Annex I, Chapter III, point 23.4 to the MDR, may be provided by manufacturers in electronic form. It also establishes certain requirements concerning contents of websites and instructions for use that are provided in electronic form in addition to instructions for use in paper form.

The Commission Implementing Regulation can be found here.

MDCG 2021-28 Substantial modification of clinical investigation under Medical Device Regulation

This guidance contains a practical form for the notification of substantial modifications of a clinical investigation under the MDR.

Under the MDR, the sponsor of a clinical investigation is required to notify the Member State(s) in which a clinical investigation is being, or is to be, conducted if it intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, within one week, by means of EUDAMED. However, as EUDAMED is not yet fully functional, MDCG has created a series of clinical investigation application/notification documents to support clinical investigation procedures with respect to MDR until EUDAMED is ready.
The guidance however states that it is important to check with the individual Member State in which the clinical investigation is taking place or planned to be conducted as to any specific national requirements that may apply. It also adds that this template will be withdrawn once the EUDAMED module for clinical investigations is fully functional.

The MDCG 2021-28 can be found here.

MDCG 2021-27: Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/74

The Medical Device Coordination Group (MDCG) has endorsed a series of questions and answers on requirements related to importers and distributors under Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices. The questions covered by the document aim to provide further detail on the operational and practical implementation of Articles 13 and 14 and other related obligations for importers and distributors under the Regulations.

The MDCG 2021-27 can be found here.

On-site audits during COVID

Since the onset of COVID and the restrictions that came with it, we have closely followed the national and international guidance on travel which has, since March 2020, resulted in a majority of audits being conducted remotely. In order to conduct audits remotely, we have been undertaking risk assessments and extending sampling to ensure that these audits have been effective.

There are, however, some audits that are required to be on-site. These audits include Stage II audits, all MDR audits, MDSAP audits, Unannounced Audits, audits of new facilities, and audits where there have already been 2 remote audits. Where we have assessed that it is safe to travel and following any national or international COVID restrictions/guidelines, we have now resumed onsite audits.

Please can we remind you to advise us if you (or any of your critical suppliers) continue to be unable to host an on-site audit.

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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.