Client Newsletter

Medical Device Regulatory Updates

PUBLISHED MDCG GUIDELINES:

- **MDCG 2022-5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices**

The MDCG published the Guidance MDCG 2022-5 which aims to establish the demarcation between the two legal frameworks established in Regulation (EU) 2017/745 on medical devices and Directive 2001/83/EC on medicinal products for human use.

This guidance provides explanations, definitions and examples clarifying the borderline between medical devices and medicinal products. Chapters are dedicated to herbal products, substance-based devices and medical devices and medicinal product combinations.

This document, developed by an expert working group, aims to support a uniform implementation of the MDR across the EU and may be revised to reflect up-to-date scientific and technical knowledge as well as the outcomes of the regulatory discussions within the MDCG Working Group on borderline and classification of these devices.

Link to MDCG: https://health.ec.europa.eu/document/download/b5a27717-229f-4d7a-97b1-e1c7d819e579_en?filename=mdcg_2022-5_en_0.pdf

- **MDCG 2022-7 – Questions and Answers on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 May 2022**

MDCG guidance aims to help manufacturers implement UDIs under MDR and IVDR.

The European Commission's Medical Device Coordination Group (MDCG) on 20 May issued a question-and-answer guidance to help the medical device industry comply with unique device identification (UDI) requirements under the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). This document covers 25 questions regarding UDI device identifiers (UDI-DI), UDI labeling, UDI rules for systems and procedures packs and configurable devices, and whether UDI rules apply to retail point of sale, promotional packs and marketing samples.
The guidance addresses whether new UDI-DIs are required for device packaging changes, such as changing the number of devices in a package from five to ten. MDCG specifies that these changes would necessitate a new UDI-DI, stating that "a change in pack quantity would lead to a misidentifying of the device in this case and may cause traceability issues where incidents occur." The guidance states that the UDI carrier needs to be placed on the label of the device itself and on all higher levels of packaging.

Link to MDCG: https://ec.europa.eu/health/system/files/2022-05/mdcg_2022-7_en.pdf

New Regulatory framework for medical devices in the UK:

- **The government's response to the consultation on the future regulation of medical devices in the United Kingdom**

The governments response to the consultation was published on 26 June 2022. The new regulation will come into force in 2023 and there are significant measures enabling products which have CE or UKCA mark to remain into force for a period of 3 to 5 years.

The consultation sets out proposed changes to the UK medical device regulatory framework with the aim to "develop a world-leading future regime for medical devices that prioritises patient safety while fostering innovation."
The aim was to seek views on developing a future legislation for medical devices which delivers:

- Improved patient and public safety
- Greater transparency of regulatory decision making and medical device information
- Close alignment with international best practice, and
- More flexible, responsive and proportionate regulation of medical devices

The MHRA will gradually phase in the new requirements, yet to be published and enforced, to give industry enough time to adapt to the changes based on the transitional arrangements which includes:

- General medical devices (MDs) and in-vitro medical diagnostic devices (IVDs) that are CE marked under EU MDR or EU IVDR may continue to be placed on the GB market until either the certificate expires or for five years after the new regulations take effect, whichever is sooner, with a view to reviewing this provision at the end of the five-year period. This will apply even if the certification/declaration of conformity is dated after the new regulations take effect.

- General medical devices and IVDs that are CE marked under EU MDD, EU AIMDD, or EU IVDD may continue to be placed on the GB market until either the certificate expires, or for three years (general medical devices) or five years (for IVDs) after the new regulations take effect, whichever is sooner.

As well, in both the cases above of CE-marked devices covered by these arrangements:

- Devices that are subject to significant changes in design or intended purpose will be excluded from these provisions

- **MDCG 2022-11 MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR requirements**

  In order to ensure that devices can continue to be placed on the market and to avoid shortages of medical devices, it is essential that all manufacturers adjust their system, finalise transition to the MDR and apply to a notified body, submitting complete and compliant applications, as soon as possible and well in advance of the end of the transition period to ensure timely compliance with the MDR.

  Link to MDCG: https://health.ec.europa.eu/document/download/5ec4d600-d344-4232-9371-1d278b2abc12_en?filename=mdcg_2022-11_en_0.pdf

NEWS FROM EU-COMMISSION

- **Commission Notice: The 'Blue Guide' on the implementation of EU product rules 2022 (Text with EEA relevance) 2022/C 247/01**

This new version of the Guide builds on the past editions and applies for EU products based on different sectors including medical devices, it reflects recent changes in the legislation and in particular the adoption of a new Regulation on Market Surveillance. Section 7.6.6. is specifically related to medical devices: vigilance system.
In general, this blue guide is putting more context in the economic operators including the clarifications of their roles and responsibilities.
This Guide is intended to contribute to a better understanding of EU product rules and to their more uniform and coherent application across different sectors and throughout the single market. It is addressed to the Member States and others who need to be informed of the provisions designed to ensure the free circulation of products as well as a high level of protection throughout the Union (e.g., trade and consumer associations, standardisation bodies, manufacturers, importers, distributors, conformity assessment bodies and trade unions). It is built on consultation among all the interested parties.

Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG&toc=OJ%3AC%3A2022%3A247%3ATOC

- **EUDAMED State of play – Additional delays in EUDAMED**

European Commission expects EUDAMED to be fully ready by Q2 2024 and published in the OJEU. This would mean that Q2 2026 will be the end of the 24 months transitional period after publication of the notice in the OJEU, hence the use of EUDAMED is expected to become mandatory as regards obligations and requirements related to UDI/Device and NB & Certificate modules in Q2 2026.
Link: https://health.ec.europa.eu/system/files/2022-07/md_eudamed_timeline_en.pdf

- All post-market requirements applicable to the new regulatory framework must be complied with for all products which benefit from the transitionary arrangements

Reference:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1085333/Government_response_to_consultation_on_the_future_regulation_of_medical_devices_in_the_United_Kingdom.pdf

EU-Turkey customs union agreement in the field of medical devices

The establishment of the Customs Union of the EU and Turkey has been done gradually and applies to both MDR and IVDR. Manufacturers established in the EU have no obligation to designate an authorised representative in Turkey in order to place devices on the Turkish market and vice versa.
For more information: https://health.ec.europa.eu/system/files/2022-04/md_eu-turkey_customs-union_en.pdf

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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.