RA news round-up
CW 28 of 2021

Europe

Q&A about Registration in EUDAMED

The MDCG has published a very interesting document on registration in EUDAMED. It doesn't answer the obvious questions that have long been discussed. Rather, it addresses the requirements for manufacturers, authorized representatives and importers that are not mentioned in Article 31 of the MDR or Article 28 of the IVDR. These include, but are not limited to, custom made, legacy and old device manufacturers.

So this Q&A is aimed at only a few companies, as the requirements are certainly clear for most stakeholders. Nevertheless, it is worth taking a look here. A Commission Implementing Regulation is also announced, which shall sufficiently define the registration in EUDAMED for all stakeholders.

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021-13_q-a-actor_registr_eudamed_en.pdf

The European Nomenclature for Medical Devices

The MDCG Guidance 2021-12 has undergone a visual make-up. The document, which answers questions about the European Medical Device Nomenclature (EMDN), is not only informative, but finally also nice to look at. Those who have not read the document so far may now have another reason.

At the latest when the Device Registration Module in EUDAMED goes online (announced for September), the document could become helpful. Namely, it explains the structure of the database and how to use it when registering devices in EUDAMED, which is required by both MDR and IVDR. The document can be found here:

https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_q-a_emdn_en.pdf

The nomenclature can be viewed on the page of the European Commission:

https://webgate.ec.europa.eu/dyna2/emdn/

Explanatory note on IVDR codes

Besides answering questions on the European Nomenclature the MDCG also took care of the IVDR codes. These are needed mainly for the designation of Notified Bodies, but are also helpful for manufacturers. Especially when choosing a Notified Body to ensure that all codes are covered by the NB.

The guidance MDCG 2021-14 describes the different type codes and explains which and how many codes are to be assigned to each device. For those eager enough to read until chapter 5 of the guidance, each code is equipped with device examples and special considerations for the code.

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021-14-guidance-ivdr-codes_en.pdf

International News

USA

Cybersecurity and Servicing

In the last issue of the qtec RA news round-up, we reported that Joe Biden had given cybersecurity a new priority by decree. The implementation in the field of medical device technology is not long in coming: currently a document of the FDA is open for discussion, which examines the cybersecurity of medical devices in connection with servicing activities.

So far, four topics (privileged access, identification of cybersecurity vulnerabilities and incidents, prevention and mitigation of cybersecurity vulnerabilities, and product lifecycle challenges and opportunities) have been identified for increased attention. Those wishing to comment on these topics have until Aug. 17th to do so.

https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/discussion-paper-strengthening-cybersecurity-practices-associated-servicing-medical-devices?utm_medium=email&utm_source=govdelivery

The Difference between Servicing and Remanufacturing

While you're at it, you can also comment on the next FDA document. This one is about remanufacturing, which should not be confused with the previously discussed servicing.

The 35-page document explains the differences, gives examples, and summarizes the requirements, which include labeling. The document is open for comments until August 23rd.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices?utm_medium=email&utm_source=govdelivery

Form and Content of the Unique Device Identifier

The document on the US Unique Device Identification System can no longer be commented on. The final version of this document is now available - five years after it was first published.

It contains explanations of the FDA's requirements for the UDI with regard to the form and content of the number. The document is intended not only for manufacturers, but for all stakeholders, who apply labels and also to certified issuing agencies.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-system-form-and-content-unique-device-identifier-udi