RA news round-up
CW 15 of 2023

Europa

Extension of transitional period

It was a bang with notice and certainly not a few medical device manufacturers were relieved: at the end of March, the transition periods of the MDR and IVDR were extended, and a sell-off period was completely suspended. The requirements from Article 120 remain in place, but many products now have a while longer to comply with all articles of the MDR or IVDR.

Exactly what deadlines now apply to which products, what the practical hurdles are, and what exemptions apply are discussed in the MDCG's Q&A document. This has 10 pages and is surprisingly comprehensive. Even the question of the appropriate QM system is answered.

The document is published on the website of the European Commission:

https://health.ec.europa.eu/system/files/2023-03/mdr_proposal_extension-q-n-a_0.pdf

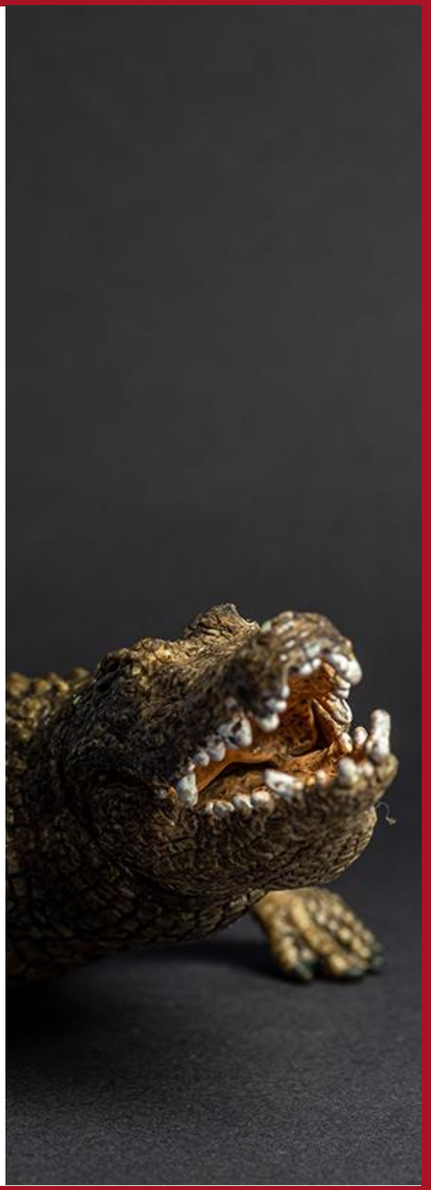
By the way: with SZUTEST Konformitätsbewertungsstelle GmbH the 38th Notified Body has just been designated.

Initiative on possible Master UDI

It is still possible to give your opinion on a possible Master UDI for a few days. An initiative is currently trying to circumvent the allocation of a UDI for highly individual products by allocating a so-called Mast UDI instead. Contact lenses, for example, could be affected. How this should look like is described in a Draft Guidance, which can be commented until April 19.

Click here for all information:

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13299-Medical-devices-single-identifier-for-similar-highly-individualised-devices_en



International News

USA

Recommendations for Artificial Intelligence/Machine Learning

Who hasn't played around with one of countless tools that conjure up an essay on the French Revolution or a photo-realistic image of the Pope in a stylish Moncler jacket in a matter of seconds? Artificial intelligence, or machine learning, is also increasingly being used in medical devices. The FDA's guidance, which is now available, presents recommendations for the associated documentation for modifications.

The scope includes modifications that are performed manually, i.e., by development engineers, and modifications that are performed automatically by AI and are already implemented in the software. The focus of the guidance is the so-called Predetermined Change Control Plan, which documents these modifications including the methods used. In addition, the PCCP is to assess the impact on the safety of the device.

The document is currently in draft status and, like all FDA documents, can be found on the FDA website:

https://www.fda.gov/media/166704/download

Marketing documentation for Cybersecurity

As of March 29, Section 524B of the Federal Food, Drug, and Cosmetic Act on cybersecurity of medical devices is in effect. This guidance reproduces the text of the law and contains a few recommendations on how to comply with the new requirements. Currently, there is still a transition period in which the FDA is willing to discuss the documentation of affected manufacturers. However, as of October 01 of this year, manufacturers must comply with the requirements of Section 524B - otherwise they face a "refuse to accept".

The guidance is available for download:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-refuse-accept-policy-cyber-devices-and-related-systems-under-section?utm_medium=email&utm_source=govdelivery

Switzerland

Adaptation of the MepV and IvDV to European transition periods

A few days after the European Commission approved the proposal to extend the transitional periods, Swissmedic also made adjustments to prevent a supply shortage. However, the changes are not to be incorporated into the Medical Devices Ordinance and the Ordinance on In Vitro Diagnostic Medical Devices until this fall. Until then, Swissmedic will tolerate the placing on the market of products that have been placed on the EU market with the help of the extended transition periods.

The notification is published here:

https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/marktzugang/abgelaufene_bescheinigungen.html

United Kingdom

Guidance on Software and Artificial Intelligence

In line with the recent publication of the FDA, the MHRA has published a Guidance on Software and Artificial Intelligence (AI). It is not dedicated to a specific topic but provides an overview and compiles all available information.

The text is therefore peppered with references to general topics from medical technology (Creating an Intended Use statement) and AI-specific topics (Good Machine Learning Practice). Now the thing is that some of the linked documents are not very detailed and helpful in daily practice. However, in the course of the Software and AI as a Medical Device Change Program Roadmap, a clear regulatory framework should be established.

All information can be found on the following website:

https://www.gov.uk/government/publications/software-and-artificial-intelligence-ai-as-a-medical-device/software-and-artificial-intelligence-ai-as-a-medical-device