RA news round-up
CW 32 of 2021

Europe

List of harmonized Standards under MDR

The latest issue starts with a rather sobering announcement. Although the European Commission has published a list of harmonized standards under the MDR, it contains only five entries.

In addition to EN ISO 10993-23:2021, four standards for sterilization of medical devices are listed. We would have hoped for a more comprehensive list of widely applied standards, but at least a first step has been taken.

https://eur-lex.europa.eu/eli/dec_impl/2021/1182/oj

Integration of the UDI within a QM-System

MDCG Guidance 2021-19 is entitled "Guidance note integration of the UDI within an organization's quality management system". As the title suggests, the document contains useful guidance on the practical implementation of the UDI requirements of the MDR in connection with the quality management system.

Specifically, the document includes considerations on the interfaces to development, production, procurement and, of course, EUDAMED. Two annexes also contain an exemplary UDI process and an implementation plan. This is certainly one of the most useful Guidances of this year so far.

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-19_en.pdf

International News

Worldwide

Recognition of CABs

The IMDRF has published a new document on the recognition of Conformity Assessment Bodies - i.e. Notified Bodies. It formulates requirements for the initial recognition process, but also describes the ongoing monitoring, re-recognition and even the withdrawal of accreditation.

The appendix also contains a table with the previously established requirements of the document. One of three grades is assigned for non-conformity, depending on the severity. The guidance document has been published on the IMDRF site:

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-210624-wng66.pdf

Myanmar

Website online again!

Good news from Myanmar: after the military coup and the subsequent shutdown of the Myanmar FDA website, it is now back online! Most of the content is still only available in Burmese, but we are happy nevertheless.

https://www.fda.gov.mm/

India

Classification of devices pertaining to anesthesiology

We hear little from India from a regulatory perspective. But now, a list has been published that serves to classify devices from the field of anesthesia in accordance with the Medical Devices Rules, 2017. In ten pages, 112 medical devices are classified into four risk classes. An explicit Intended Use is provided for each device. Unfortunately, there is no detailed explanation of the application of the document.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQyNg==

Australia

Consultation

Australia has meanwhile earned a regular place at this position. In the meantime, however, medical device reform has almost been completed. The regulation of substances intended to be inserted into the body through an orifice or applied to the skin as medical devices is still open.

A consultation procedure has now been opened, but it will only be open until mid-August. Anyone wishing to comment on the document presented can do so in the recently opened Consultation Hub:

https://www.tga.gov.au/consultation/consultation-proposed-refinements-regulation-medical-devices-are-substances-introduced-human-body-body-orifice-or-applied-skin

Singapore

Consultation on SaMD and CDSS

The Health Science Authority (HSA) of Singapore has published a document on the classification of standalone medical mobile applications (SaMD) from A to C The risk based criterias for the classification based on the State of healthcare situation or condition and the significance of information provided by SaMD to healthcare decision

As an aside, the question of the qualification of clinical decision support software (CDSS) as a medical device is also answered.

The document is in draft status until August 19 and can still be commented on until then. More info can be found here:

https://www.hsa.gov.sg/announcements/regulatory-updates/consultation-on-regulatory-guidelines-for-classification-of-standalone-medical-mobile-applications-(samd)-and-qualification-of-clinical-decision-support-software-(cdss)

Kanada

Classification of products at the drug-medical device interface

Canada has revised its document on the classification of combination products. These products "at the drug-medical device interface" are classified by the Canadian Food & Drugs Act, which consists of four Regulations. Which of these regulations applies to this class of products is explained in this document.

The guidance was originally published in 2013, so this first proper revision was more than overdue:

https://www.canada.ca/en/health-canada/services/drugs-health-products/classification-health-products-device-drug-interface/guidance-document-factors-influencing-classification-products-device-drug-interface.html#a2

China

Standards Revisionsprogram

China has announced a major revision program of its standards in the medical device sector, comprising a total of 77 documents. Together with the announcement of the revision, a document with an overview of the current status was also published, which will hopefully receive regular updates. As expected, all the information is in Chinese, but fortunately various translation options are available free of charge.

https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjylqx/20210707141730119.html