RA news round-up
CW35

Europe:

A new notified body under the MDR was designated:
DQS Medizinprodukte GmbH (NB 0297) was approved to perform medical device certification under the MDR 2017/745. The German conformity assessment body offers certification e.g. for

- Active implantable devices for stimulation/inhibition/monitoring
- Active non-implantable devices, e.g. for devices utilizing ionizing radiation, shock-wave therapy or ophthalmology
- Software
- Non-active non-implantable devices, e.g. for orthopedics and rehabilitation

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.html&ntf_id=308392&version_no=9

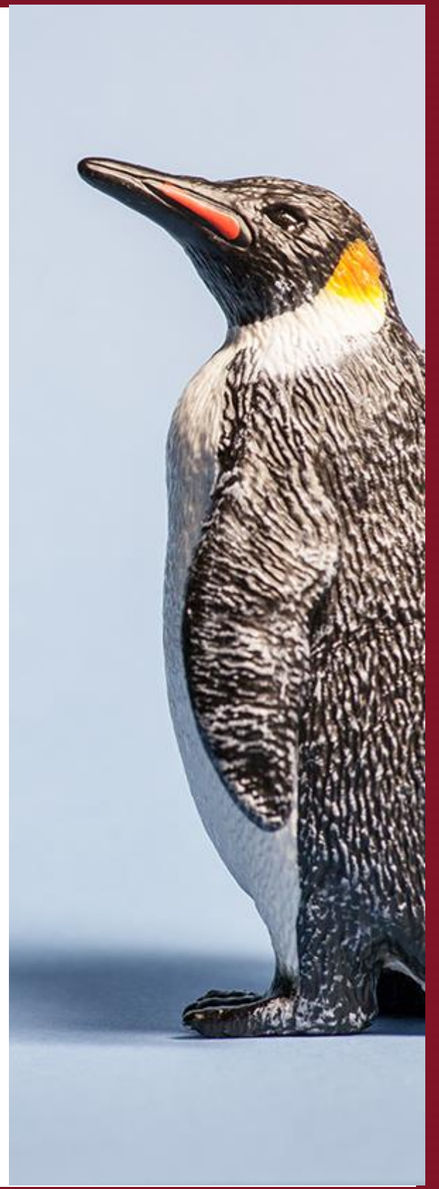
The European Commission provided a **FAQ** about the **Unique Device Identification (UDI) System** under the MDR and IVDR. Building up a UDI system is one of the big new challenges medical device manufacturers have to face under the regulations 2017/745 and 2017/746.

The objectives of that system are

- easier traceability of medical devices,
- enhance the effectiveness of the post-market safety-related activities for devices and
- allow better monitoring by authorities.

Pending on the risk class there are different timelines for the obligation for placing the UDI carrier. The FAQ gives a good overview about these and other information and facts every manufacturer of medical devices should be aware of.

https://ec.europa.eu/docsroom/documents/42641?locale=de



Corona related news (excerpt):

The **FDA** issued an umbrella emergency use authorization (EUA) for surgical masks due to insufficient supply and availability of such masks. Surgical masks that meet the criteria under the EUA are listed in the Appendix A. The *Surgical Masks EUA Template for Addition to Appendix A* can be used to provide the information requested in the EUA to the FDA.

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas?utm_campaign=2020-08-07%20CDRH%20New&utm_medium=email&utm_source=Eloqua#appendixasurgicalmasks

The **Australian TGA** provides information about face masks and respirators that are regulated by the TGA for guidance to help determine when a face mask is a medical device and therefore must be included in the Australian Register of Therapeutic Goods (ARTG). There are also information that help to interpret labelling claims.

https://www.tga.gov.au/face-masks-and-respirators-are-regulated-tga

International news

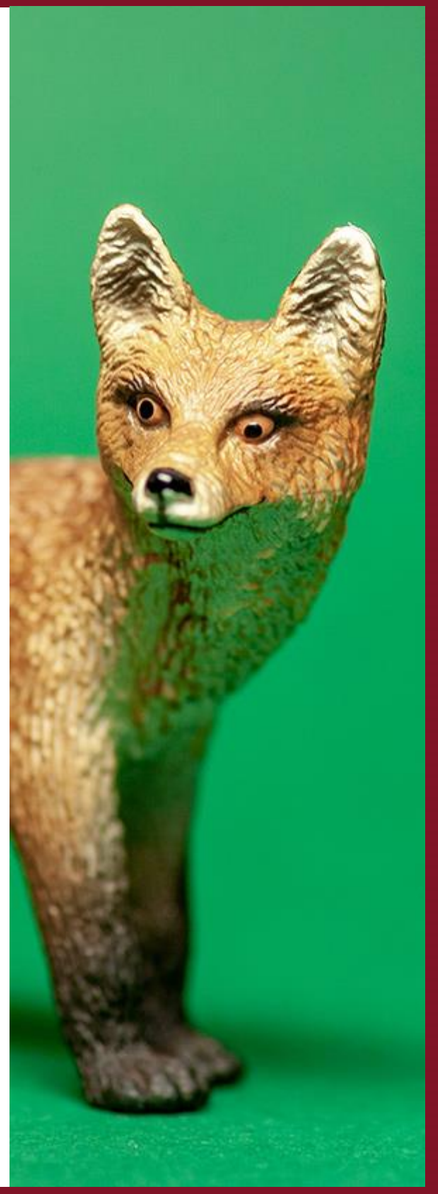
Russia:

The Russian government published a resolution that they call the "regulatory guillotine". It is a tool for large-scale revision and cancellation of regulatory legal acts and a total revision of mandatory requirements for medical devices. The guillotine affected e.g. the following fields:

- Post-market surveillance
- Licensing of production and maintenance activities
- The circulation of counterfeit, substandard and counterfeit medical products

It will also cancel 11 other minor regulations for medical devices. New rules and systems will be set up taking into account the risk-based approach and the current level of technological development in the relevant areas.

https://www.economy.gov.ru/material/directions/gosudarstvennoe_upravlenie/mehanizm_regulyatornoy_gilotiny/



The Russian Ministry of Health published a new version of the regulation on the examination of medical devices as a part of the registration process. The regulation describes examination procedures of medical devices depending on the type of submission and the risk class.

https://www.fedlab.ru/upload/medialibrary/0ed/Prikaz-MZ_poryadok-provedeniya-ekspertizy-kachestva_-effektivnosti-i-bezopasnosti-MI_22.06.20.pdf

The government in **Kazakhstan** released similar changes to their medical device regulation.

https://online.zakon.kz/Document/?doc_id=35231195

The **Eurasian Economic Commission** published a draft version of a regulation on technical testing requirements for Eurasian registration procedures which describes testing procedures for medical devices.

https://docs.eaeunion.org/ria/ru-ru/0104092/ria_09072020

Australia:

The TGA published the document "Analysis of submissions from the consultation: Scope of regulated software based products" which summaries the feedback about the initiative of removing some software medical device products from regulatory oversight by the TGA.

https://www.tga.gov.au/sites/default/files/consultation_submissions_analysis-scope_of_regulated_software_based_products.pdf