RA news round-up
CW19 of 2021

Europe

Factsheet for Class I Medical Devices

On three pages the MDCG has summarized the most important information of the MDR for manufacturers of Class I medical devices. The so-called *factsheet* addresses practical problems and presents the information in an easy-to-understand manner. For our customers, of course, that's an old hat. However, the document can be a helpful overview, especially for foreign companies.

https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_mdcg_2021_factsheet-cl1_en.pdf

Guidance on BASIC UDI-DI and changes to UDI-DI

The MDCG's Guidance 2018-1 is already a few days old. Now, however, the document has been given a makeover with the fourth revision. In the document, both the BASIC UDI-DI and changes to the UDI-DI are explained in more detail.

https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018-1_guidance_udi-di_en.pdf

BSI has published a remarkable news article. The British Standards Institution was the first designated Notified Body for the Medical Devices Regulation and has now grown to 450 employees. Apparently, however, even this number is barely enough to meet the increased demand for auditors due to the requirements of the MDR and IVDR.

Therefore, BSI has now published an overview of the internal deadlines for the submission of technical documentation. It is pointed out that these are not the dates for a first-time submission to the company. In fact, BSI only confirms their effort to issue a certificate by the end of the respective transition periods if the deadlines are met.

The article and the table with the corresponding dates can be found here:

https://www.bsigroup.com/en-GB/medical-devices/news-centre/enews/2021-news/technical-guidance-to-meet-your-ivdrmdr-timelines/

International News

India

Which medical devices must be registered in India is determined by the Central Drugs Standard Control Organization (CDSCO). Since April of this year, the list of devices requiring registration has grown by eight entries. As announced earlier in 2019, the following medical devices must also be registered now:

- All implantable medical devices
- CT Scan equipment
- MRI equipment
- Defibrillators
- PET equipment
- Dialysis machines
- X-Ray machines
- Bone marrow cell separators

In addition, a transitional period of 6 months was determined, which allows manufacturers and importers of such products to continue to distribute and import them, although the registration procedure has not yet been completed.

The order can be found here:

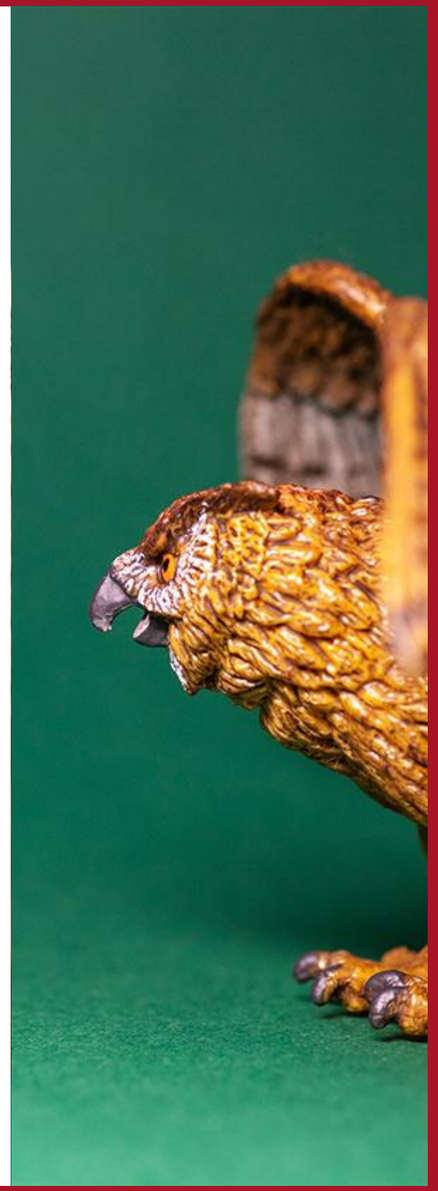
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0Nw==

Singapore

In mid-April, eight cybersecurity vulnerabilities were discovered in the well-known TCP/IP network stacks FreeBSD version 12.1, Nucleus NET version 4.3, NetX version 6.0.1 and IPnet version VxWorks 6.6. This announcement made headlines around the world and medical devices may also be affected. The discovery by Forescout goes by the name "Name:Wreck". There are no known attacks on these gaps - but depending on the type of device, the potential damage can be high.

The Health Sciences Authority of Singapore has responded by issuing an announcement that indicates suggested courses of actions for affected medical device manufacturers. It also refers to the Forescout's report:

https://www.forescout.com/research-labs/namewreck/



The HSA document is available at the following link:

https://www.hsa.gov.sg/docs/default-source/announcements/safety-alerts/md-advisory_cybersecurity-vulnerabilities-(name-wreck)-affecting-four-tcpip-network-stacks-in-medical-devices.pdf

Taiwan

Taiwan has introduced new administrative fees and charges for medical equipment. For example, the testing of novel devices costs around 7400 euros. A certificate renewal is already available for around 240 euros. The new fee standards will apply to all medical devices as of May. Since the list has not yet been published in English, it is advisable to use a translation tool.

https://www.fda.gov.tw/TC/newsContent.aspx?cid=3&id=26973