



RA news round-up
CW 11 of 2022

International News

India

List of notified bodies published

The Medical Device Rules 2017 of the CDSCO have been in force in India since January 2018. The regulations are based on the recommendations of the IMDRF and accordingly there are also notified bodies in India that are responsible for the approval of medical devices and in vitro diagnostics.

Now a list with an up-to-date overview of all ten Notified Bodies in India has been published. As is often the case with the Indian authorities, this is only a non-searchable printout.

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

Classification of instruments

Fortunately, the following much longer list from the Indian CDSCO is searchable: "Classification of Medical Devices Pertaining to General Hospital/Orthopaedic Instruments". According to the Medical Devices Rules 2017, the classification

works by lists based on the Intended Use of the respective product. The list of general hospital and orthopaedic instruments was recently published and divides 133 groups into the four classes. The list can be found at the following link:

https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Classificationg1.pdf

Malaysia

Guidance on personal protective equipment

In Malaysia, personal protective equipment is partly subject to the requirements of the Medical Device Act 2012 (Act 737) or the Medical Device Regulations 2012. This is of course related to the intended purpose of the protective equipment. However, an incorrect marketing claim can also lead to the sudden application of the above-mentioned regulations.

Guidance from the Malaysian Medical Device Authority is now available for comment to provide an overview of the requirements for personal protective equipment. Comments can be submitted via a separate form until March 25.



<https://portal.mda.gov.my/announcement/887-public-comment-draft-medical-device-guidance-document-personal-protective-equipment-ppe-requirements.html>

Canada

Adjustment for case of shortages

In the last issue, there was a very similar article about Section 506J of the US FD&C Act. Now it is up to the Canadian authorities to make regulatory adjustments to prevent a possible shortage of medical devices or drugs.

Supposedly, the shortage of such products is an ever-growing, worldwide problem. Triggered by the Covid 19 pandemic, Interim Orders (IOs) have been used in the past two years, but they expire after one year. With the new regulations, the required IOs will be maintained. In addition, exports from Canada could be restricted in the future.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/notice-amending-regulations-drugs-medical-devices-shortages.html>

