REGULATORY NEWSLETTER

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What's New?

EU IVDR Classification Guidance Released by MDCG

The MDCG has published "MDCG 2020-16 rev.3 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746"

The primary purpose of this document is to provide guidance to manufacturers, notified bodies and health institutions on how to classify an IVD prior to placing it on the market, making available on the market or putting into service in the Union. It is also intended to inform regulators and other stakeholders when assessing the class attributed to an IVD by a manufacturer or a health institution.

https://health.ec.europa.eu/document/download/12f9756a-1e0d-4aed-9783-d948553f1705_en?filename=md_mdcg_2020_guidance_classification_ivd-md_en.pdf

MDCG released updated guidance on Standardisation for medical devices

The Artificial Intelligence Act has been published in the Official Journal of the European Union (OJEU).

The new law categorises different types of artificial intelligence according to risk. AI systems presenting only limited risk would be subject to very light transparency obligations, while high-risk AI systems would be authorised, but subject to a set of requirements and obligations.

This Regulation shall enter into force on the twentieth day following that of its publication in the OJEU.

It shall apply from 2 August 2026.

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/uri=OJ:L_202401689#:~:text=The%20purpose%20of%20this%20Regulation,in%20accordance%20with%20Union%20values%2C

Top News

EU AI Act

EU IVDR Classification Guidance!

EUDAMED & IVDR Extension

EUDAMED & IVDR Extension

The regulation adopted today amends the legislation on medical devices, including IVDs, by:

- Further extending the transition period for certain IVDs
- Enabling a gradual roll-out of EUDAMED, the new electronic database
- Requiring manufacturers to flag up potential shortages of critical medical devices and IVDs

IVD devices meeting certain criteria can benefit from the following transitional period:

- **31 December 2027, for class D devices;**
- **31 December 2028, for class C devices;**
- **31 December 2029, for class B devices and for class A devices placed on the market in sterile condition**

The regulation was first proposed in January 2024 with the aim of mitigating shortages of critical medical devices. The new regulation adopted today will enter into force following publication in the OJEU. Obligations regarding interruption or discontinuation of supply of devices shall apply from 10 January 2025.

https://eur-lex.europa.eu/eli/reg/2024/1860/oj#:~:text=Regulation%20(EU)%202024%2F1860,provisions%20for%20certain%20in%20vitro

WHO and GMDN Agency Sign Agreement

The World Health Organization (WHO) and the Global Medical Device Nomenclature (GMDN) Agency announce a new collaboration to improve the management and safety of medical devices used around the world. The landmark new relationship will initially see the WHO using 3,000 GMDN Terms, Codes and Definitions within its online medical device information platforms such as the MeDevIS (Priority Medical Devices Information System), an open access WHO electronic database of medical devices.

The agreement between the two organisations will see colleagues from the GMDN providing support to the WHO via consultation, database management, data analysis, and ensuring the nomenclature is up to date and accurate on WHO platforms and helping with any WHO publications that reference GMDN.

U.S. FDA Draft Guidance on the Purpose and Content of URRAs for Medical Products.

The FDA issued a new draft human factors engineering (HFE) guidance document, Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products, on July 8, 2024. The guidance informs manufacturers of drug- and biologic-led combination products about the purpose and content of a use-related risk analysis (URRA) and how a URRA informs other human factors (HF) activities and can be used to support a marketing application or justification to forgo submitting HF validation study results. The benefit of this new draft guidance is that it organizes and consolidates all risk analysis information into one document.

https://www.fda.gov/media/179858/download

EU Dealine for Batteries!!

By August 18, 2024, portable batteries need to be compliant with the EU Battery Regulation 2023/1542. This implies that portable batteries must possess the technical documentation for compliance to relevant articles of the regulation, DoC, and CE marking. As a medical device or IVD manufacturer you must review for compliance of the battery and ensure there is the CE marking, or you accept responsibility as the manufacturer and affix the CE marking. In addition, it is expected that the battery and device or IVD are separately marked with the CE marking.

Team Notified Body Adopt Transfer Agreement

This agreement is executed between the manufacturer, the Notified Body that issued the MDD/AIMDD legacy device CE Certificate, and the Notified Body that is taking over market surveillance activities for that legacy device.

If the manufacturer has selected a new Notified Body for their MDR certification, and the new Notified Body agrees to take over the surveillance activities for the Notified Body of the MDD/AIMDD legacy device, this agreement is applicable.

www.team-nb.org/wp-content/uploads/2024/07/Team-NB-PositionPaper-TransferAgreement-v02-20240702-with-instructions.pdf

Health Canada Release Updates on Standards

Health Canada has proposed updates to the list of recognised standards for medical devices. Alongside this they have released "Draft guidance on using standards to support compliance with the Medical Devices Regulations"

The updated standards list has:
- A new method of version recognition using standards listed without years and editions
- 6 new standards
- 12 updated standards with notes added

The draft guidance provides guidance to manufacturers on how to use standards to demonstrate compliance with safety, effectiveness, and labelling obligations imposed by the Medical Devices Regulations.

The updates to the guidance include:
- Explains the concepts that manufacturers must apply when using standards to support compliance with the Medical Devices Regulations
- Helps manufacturers understand how to use the list of recognized standards for medical devices
- Explains the new method used for version recognition

Health Canada is looking for feedback for both the draft standards list and the draft guidance. The 60-day consultation period is from July 25 to September 23, 2024.

Draft standards list link: *https://lnkd.in/eFNKJeNk*
Draft guidance link: *https://lnkd.in/eG_QpuDn*

Team Notified Body

Team Notified Body (NB) has scheduled another MDR training session for Wednesday November 6, 2024. There are limited spaces available. Please see below for registration details:

www.team-nb.org/wp-content/uploads/2024/07/Leaflet-MDR-TD-Manufacturers-Training-20241106.pdf

Global Regulatory Updates

Germany warns against over regulation of medical devices.

Australia has released a guidance on whether a device is a cosmetic or therapeutic good.

Saudi Arabia release guidance on extended shelf life in case of public emergency.

New Zealand announce intent to repeal the Therapeutic Products Act 2023.

Brazil shares update on IVD Regulation RDC 830/2023.

Upcoming Conferences

Med-Tech Conference
15 October - 17 October 2024
Toronto, Canada

Medica 2024
11 November - 14 November 2024
Düsseldorf, Germany

American Medical Device Summit
30 September - 1st October 2024
Chicago, USA

Please reach out to us at contact@apotechconsulting.com to learn more about the impact of these updates!