Product Stewardship - Medical Devices - (to be updated)

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Introduction

A **medical device** is an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Main regulatory texts and useful links per zone/country

European Union 

Medical devices within the EU are currently regulated by three directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990);
- Council Directive 93/42/EEC on Medical Devices (MDD) (1993);
- Council Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVDMD) (1998).

On *5 April 2017,* two regulations were adopted to improve the safety of medical devices:

- Regulation (EU) 2017/745 on medical devices;
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices .

The new regulations entered into force on *25 May 2017* and will progressively replace the existing directives. They will be fully applicable in *May 2021* for medical devices and *May 2022* for in vitro diagnostic medical devices.

- The regulations provide clear criteria to define a “medical device”.
- The regulations establish requirements in terms of tests, etc.. depending on the Class of the medical device (1 to 4 - defined in annex VIII).
- Medical devices must be certified by a Notified Body for CE Marking; certifications are published on the official NANDO website.
- EC Declaration of Conformity & additional declarations are required (Annex IV).
- Basic UDI-DI (primary identifier of a device model) is referenced in the EU declarations of conformity. It gives access to basic information on medical devices in EUDAMED database.

Useful Links

- Consolidated texts of the mentioned legislation are available via the **Solvay RegWatch** portal
- European Commission: Medical Device - new regulations.

China 

In China, the main regulation is Supervision and Administration of Medical Devices (Decree of the State Council of the People's Republic of China, No. 650), which was revised in 2014.

Medical devices are classified as three categories from I to III, category I with low risk, category II with medium risk and category III with high risk.
For manufactured and imported medical device, recording is required for category I products, while registration is required for category II and III products, registration certification valid for 5 years.

Notified body is National Medical Products Administration (NMPA). Required data for registration is as following :

(1) Product risk analysis data;
(2) Product technical requirements;
(3) Product inspection report;
(4) Clinical evaluation data;
(5) Sample product manuals and labels;
(6)Quality management system documents related to product development and production;
(7) Other information required to prove that the product is safe and effective.

Meanwhile, manufacturer and operator of medical device should submit recording material or obtain a business permit, depending on the different categories of medical devices.

Korea 

In Korea, ***Medical Device Act*** (Law No. 16402, revised on April 23, 2019) applies to medical devices :

Medical devices are classified to class to according to potential risk to human health. Class devices have low risks and Class devices are high risk and complex devices.
Class I and Class II devices require certification by the Medical Device Information and Technology Assistance Center (MDITAC). Some Class II new devices, Class III, and Class IV devices require approval by the Ministry of Food and Drug Safety (MFDS).

MFDS requires the submission of 'Technical Documents' for the certification and approval of medical devices. The documents include quality of medical devices, information on raw materials, structure, purpose of use, instructions for use, principles of functions, precautions for use, test standards, etc.

People who intend to manufacture/import medical devices should obtain manufacturing/importing business licenses.

Useful Links

Ministry of Food and Drug Safety - Approval Process in Korea

Japan 

Japanese Pharmacopoeia - 17th edition (2016), bdoes not mention the content of medical devices.
https://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/JP17_REV.pdf

Mainly, medical devices are regulated by ***Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices*** .
http://www.japaneselawtranslation.go.jp/law/detail/?id=3213&vm=04&re=01

Notified body is PMDA.

Useful Links

Japanese website of PMDA

India 

Medical Devices regulation in India follows the rules and guidelines of ***Medical Device Rules*** and ***The Drugs and Cosmetics Act.*** The central government and the state government both regulate the policies of the medical devices currently. Approval in the country of origin is required for medical device registration in India. Medical devices and in vitro diagnostics (IVDs) in India are regulated under the Medical Device Rules that came into effect in 2018.

Useful Links

Regulatory Summary Sheet on Medical Devices Regulations in India

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USA 

In the USA, the ***Code of Federal Regulations, Title 21, Parts 800-1299*** gives the ***Food & Drug Administration (FDA)*** authority to regulate medical devices and provides guidance on how to comply with the provisions of the ***Medical Device Amendments Act of 1976*** .

Main Requirements fall under the following Parts:

- Establishment registration [21CFR Part 807],
- Medical Device Listing [21CFR Part 807],
- Premarket Notification 510(k) [21CFR Part 807 Subpart E], unless exempt, or Premarket Approval (PMA) [21CFR Part 814]
- Investigational Device Exemption (IDE) for clinical studies [21CFR Part 812],

Useful Links

- Product Code Classification
- Device Premarket Notification 510(K)
- Device Premarket Approval (PMA)

- Quality System Regulation (QSR) [21CFR Part 820],
- Labeling requirements [21CFR Part 801], and
- Medical Device Reporting (MDR) [21CFR Part 803].

Requirements in terms of tests are outlined by the ***Class Type*** *(I – General Controls, II – General/Special Controls or Premarket Notification, and III – General Controls/Premarket Approval)* as defined in 21 CFR 860 and detailed in 21 CFR Parts 862 through 892 with additional guidance documents per the **P roduct Code Classification** .

Canada

More information, refer to this Safe Medical Devices in Canada.

Useful Links

Safe Medical Devices in Canada

Brazil

In Brazil, **medical devices** are in a wide and diverse group of health products - in Portuguese currently as "Produtos para a Saúde" or "Correlatos" in the former definition. These materials are regulated by **Anv isa** (Brazilian Health Authority) at varying levels of complexity, including from a simple gauze pad or infrared lamp to magnetic resonance equipment or a reagent kit for HIV detection, products used in medical, dental and physiotherapy procedures, equipment for workout and fitness, aesthetics equipment, as well as in the diagnosis, treatment, rehabilitation or monitoring of patients. The basic regulation is the **Resolution Anvisa RDC 185/2001** which is in extended review process this year. These products are allocated in 4 classes and each class has its own rules and requirements

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EAEU (Russia)

There is no dedicated Technical regulation to medical devices in the frame of the Eurasian Economic Union therefore there are many separate regulations applicable such as

- Agreement on common principles and rules for the circulation of medical devices (medical devices and medical equipment) within the framework of the Eurasian Economic Union
- Decision of the Council of the Eurasian Economic Commission of February 12, 2016 N 46 "On the rules for registration and examination of the safety, quality and efficiency of medical devices"

Useful Links

Eurasian Economic Commission official website

Related texts are available via the **Solvay RegWatch** portal.

More questions? Ask them in our Discussion board or contact Patricia Villers