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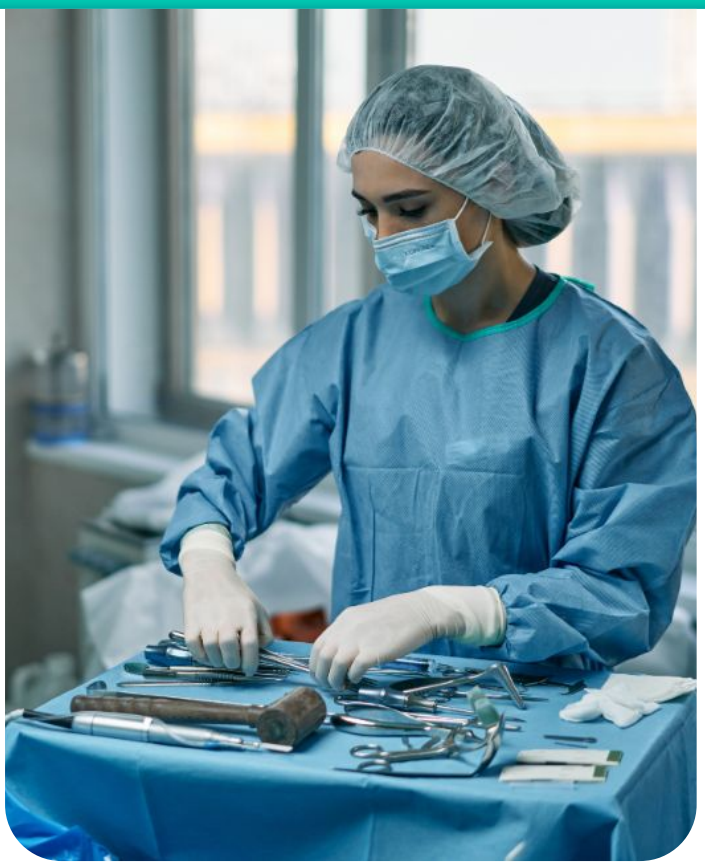

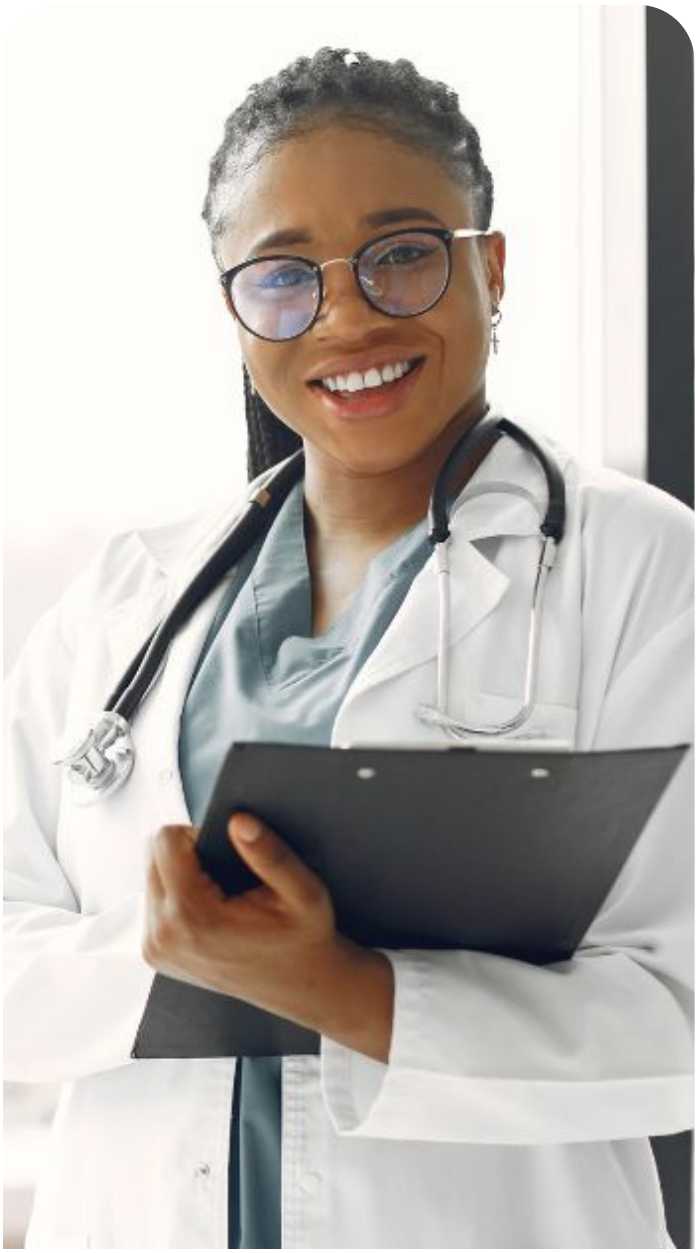

Medical Devices Regulatory Updates in North, Central and South America

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22 May, 2024

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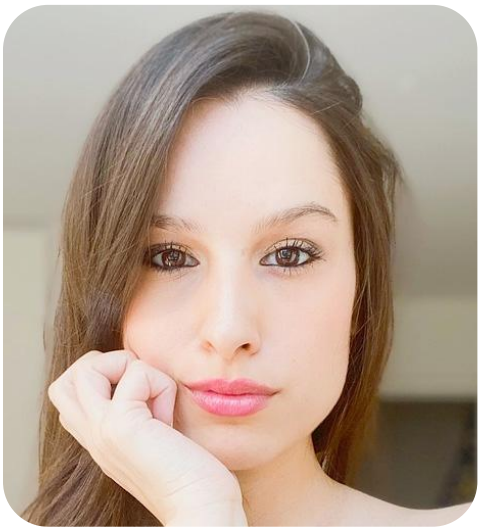

Fernanda Paro, Regulatory Compliance Specialist, Compliance & Risks

Fernanda is a Regulatory Compliance Specialist with the Global Regulatory Compliance team, responsible for the monitoring of regulatory updates in several Latin American countries and specialized in the topic of Medical Devices.

Fernanda holds a Master's Degree in International Trade Law focused on Medical Devices, Data Protection and Cybersecurity, and is a qualified lawyer, registered in Brazil and Portugal.

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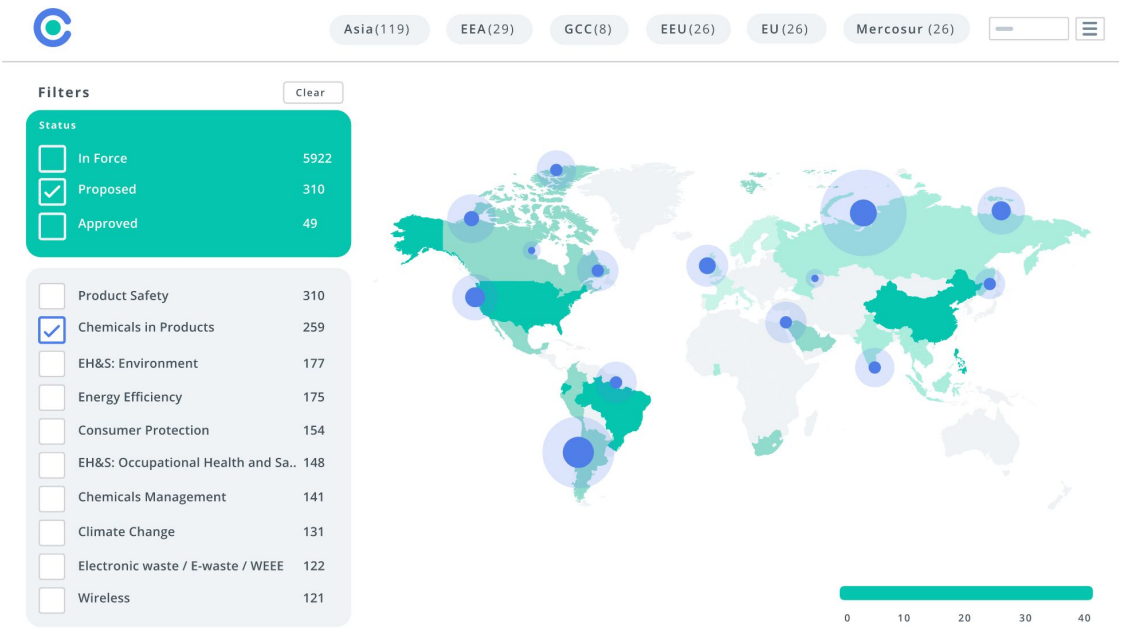

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03. Introduction

The medical devices sector has experienced significant growth in recent years, and countries are implementing an increasing number of regulations and guidelines, which is illustrated in the chart below.

The rising demand for innovative products is driving greater investment in research and development (R&D), as well as the advancement of medical technologies.

Despite this growth, the industry faces significant challenges, including intricate regulatory procedures, reimbursement limitations, and the high costs of developing cutting-edge technologies.

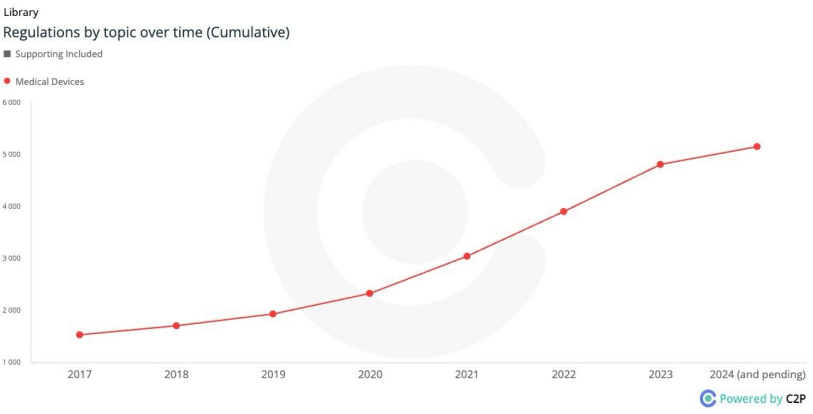
Thus, as an integral part of the healthcare world, the medical device industry must comply with a dedicated regulatory framework which is also growing and requesting more attention from those who are part of it, including manufacturers and providers, who must be aware of the regulatory approval requirements if they want to put their devices onto the market.

The process required for regulatory approval of a medical device varies based on its type and classification. These procedures range from straightforward, quick, and low-cost to highly complex, time-consuming, and demanding in terms of resources.

In the United States, all medical devices, including in vitro diagnostic devices, are governed by the Food and Drug Administration (FDA) regulations included in the US Code of Federal Regulations (CFR).

The devices are classified into three categories (Class I, II, III) and are subject to specific regulatory frameworks: 510(k) exemption, 510(k), and Premarket Approval. Besides this basic structure, the flourishing of new regulatory documents is huge and asks for attention, as we will see below.

In Latin American countries, medical device markets are under national regulations that differ from country to country. However, some similar standards are extensively harmonized among the Mercosur countries, including Argentina, Brazil, Paraguay, Uruguay, and associated countries. In contrast, Mexico, which is not a member of Mercosur, has distinct medical device regulations compared to other countries in the region.



04. North and Central America

4.1. United States

In the US, the FDA has published several relevant updates recently. Below are some of the latest regulatory updates.

Quality System Regulation Amendments

This Final Rule, published on 02 February 2024, updates the current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation. This amendment aims to harmonize and modernize the regulatory framework, to align the US standards more closely with the international consensus for devices by converging their quality management system (QMS) requirements with those used by regulatory authorities in other jurisdictions. Specifically, the FDA has adopted the ISO 13485 requirement by reference in its entirety without any modifications. However, they emphasize that compliance with ISO 13485 is just part of the entire requirements of the Quality Management System Regulations (QMSR).

Laboratory Developed Tests (LDTs)

FDA issued this final rule to clearly define In vitro diagnostic products (IVDs) as devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act), including when a laboratory manufactures the IVDs. It also includes phaseout policies.

4.2. Canada

In Canada, the Medical Devices Directorate (MDD) under Health Canada is the authority responsible for monitoring and evaluating the safety, effectiveness, and quality of diagnostic and therapeutic medical devices. Through the pre-market review, post-approval surveillance, and quality systems in the manufacturing process they can evaluate if the devices meet all the requirements needed.

Draft Guidance on How to Interpret 'Significant Change' of a Medical Device

This document has been revised to provide a more detailed explanation of what constitutes a "significant change" under the Medical Devices Regulations. It intends to assist stakeholders in determining if a modification to a Class III or IV medical device is substantial.

List of Medical Devices - Notification of Shortages

The authority has updated the list of medical devices about which manufacturers and importers must report shortages and discontinuations (or those of their components, accessories or parts) that will lead to a shortage.

4.3. Mexico

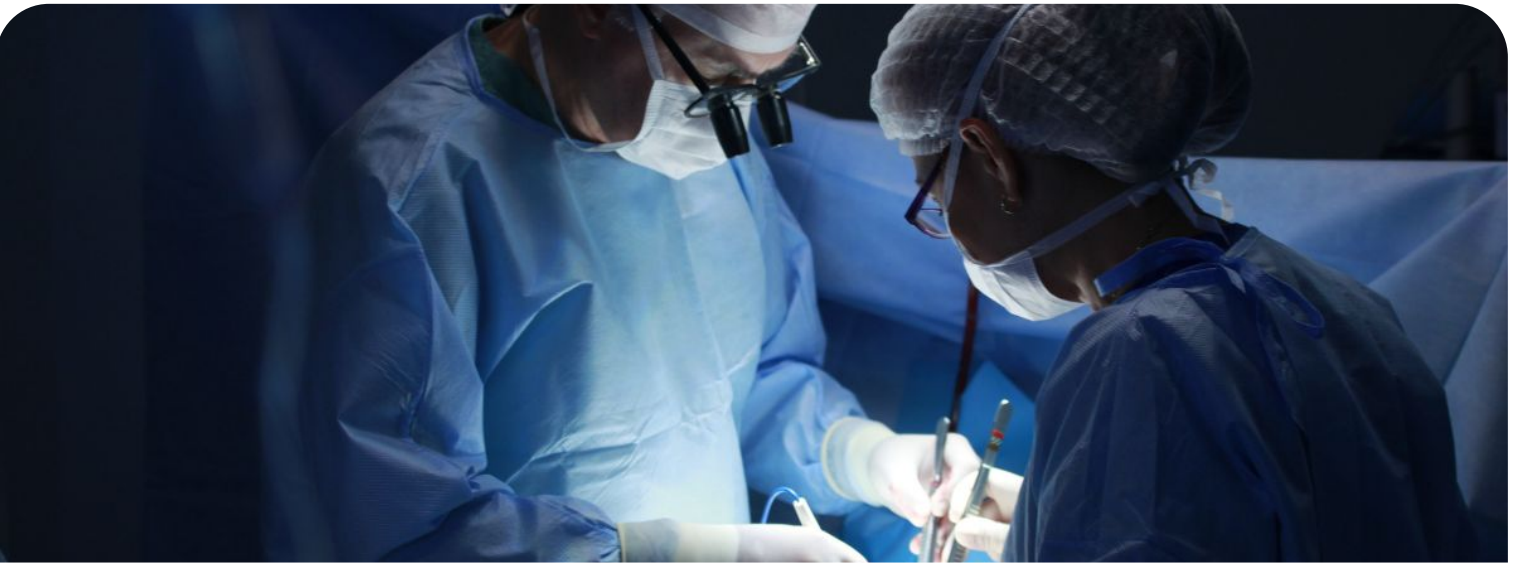
In Mexico, the Mexican Secretariat of Health is the government agency responsible for implementing national health policies and overseeing various aspects of health services, including drugs and medical devices regulation.

Under this Secretariat, COFEPRIS is the department that deals with the importation of medical devices and issues advertising permits for these products.

New Draft of NOM-137-SSA1-2024 for Medical Device Labeling

The Draft was revised again to introduce certain notable changes, including:

1. It clarifies that the country of origin of the medical device should not be confused with the actual manufacturer, which may be different. Previously, the country of origin was necessary under the earlier NOM, and though it has not been officially defined, it is typically understood to be the country from where the devices are shipped before being imported into Mexico.
2. Abbreviations are now allowed within the address details.
3. Medical devices imported as samples must be labeled following the manufacturer's Quality Management System (QMS) and must include the statement "Prohibited for sale".



05. South American Countries

5.1. Brazil

The National Health Surveillance Agency (ANVISA) regulates medical devices in Brazil.

Portaria RDC No. 848, 2024 on Essential Safety and Performance Requirements for Medical Devices and In Vitro Diagnostic (IVD) Medical Devices

This intends to define the essential principles of safety and performance as general criteria that must be met by medical devices and in vitro diagnostic (IVD) from 4 September 2024.

Normative Instruction No. 290/2024

Normative Instruction No. 290/2024 establishes a streamlined process for analyzing and deciding on applications for the registration of medical devices, specifically those that have been previously approved by an Equivalent Foreign Regulatory Authority ("AREE").

This regulation applies to the initial registration applications for medical devices outlined in Resolution No. 751/2022, and for in vitro diagnostic devices as specified in Resolution No. 830/2023, classified in Risk Classes III (high risk) and IV (maximum risk).

5.2. Colombia

In Colombia, the National Institute of Drug and Food Surveillance (INVIMA) is the authority responsible for the regulation and oversight of foods, drugs, medical devices, pharmaceutical, and biological products.

Policy on Medical Device Policy for the Years 2024-2026

On February 8, 2024, the Colombian Ministry of Health and Social Protection issued Resolution No. 184, which approved the Medical Device Policy for 2024-2026.

The core objective of this policy is to enhance equitable access to medical devices for the Colombian population.

It focuses on improving factors that influence their availability, quality, and continuity, as well as ensuring their safe and appropriate use to benefit both individual and public health.

5.3. Chile

The National Agency for Medical Devices, Innovation, and Development (ANDID) regulates and guarantees the safety and performance of medical devices, including in vitro diagnostic medical devices.

Decree No. 15/2024

Decree No. 15/2024 amends Decree No. 41/2022 on Adding the Indicated Devices for HIV Detection to the Health Control System Established in Article 111 of the Health Code to delay the implementation date of the provisions in transitional Article 2 of Decree No. 41 (regarding medical devices Class IV).

The devices affected by this postponement include:

- Instrumental assays for the detection of anti-HIV antibodies;
- Visual/rapid tests for the detection of anti-HIV antibodies; and
- Visual/rapid tests designed for HIV self-testing.

06. Global: IMDRF and Mercosur

6.1. International Medical Devices Regulators Forum (IMDRF)

The IMDRF have published 4 documents this year, including a report, a public consultation, and Guidance Documents, as follows:

Guidance Regarding Information to be Included

This aims to identify the type of information Conformity Assessment Bodies would be expected to review during evaluation of a regulatory submission and to be used in evaluating a regulatory submission consistent with other IMDRF guidance, namely, IMDRF/RPS WG/N9.

Guidance on Principles of Labeling for Medical Devices and IVD - Edition 2

This intends to provide globally harmonized labeling principles for medical devices, including in vitro diagnostic (IVD) medical devices.

Guidance on Essential Principles of Safety and Performance of Medical Devices and IVD

This aims to identify and describe essential principles of safety and performance that should be considered during the design and manufacturing process.

Public Consultation on Medical Device Software - Considerations for Device and Risk Characterization

This promotes and informs clear and accurate characterizations of medical device software (including intended use/intended purpose statements) and introduces a general strategy for characterizing software-specific risks that leverages the key features of a comprehensive medical device software characterization.

6.2. Mercosur

Resolution MERCOSUR/GMC/RES No. 7/24 on Safety and Performance Requirements for Medical Devices and In Vitro Diagnostic Medical Devices

This outlines the essential safety and performance criteria for both medical devices and in vitro diagnostic medical devices and applies to all medical devices and in vitro diagnostic medical devices.

It aims to identify and detail the fundamental safety and performance principles that must be considered during the design and manufacturing processes.

The Resolution also deals with labeling requirements and others.

10. Conclusion

This whitepaper summarizes some of the key recent regulatory updates impacting medical devices.

There are many more regulatory developments expected in the coming years focusing on artificial intelligence, software regulation, and e-labels/UDI.

Compliance deadlines for updating essential safety and performance requirement checklists per RDC 848/2024 are fast approaching.

In the US, further guidance is expected on cybersecurity and software, and in Canada they are exploring a regulatory initiative on principles of good machine learning practice for medical devices.

At Compliance & Risks, we continuously monitor regulatory developments in medical devices in our C2P platform.

References:

- Quality Management System Regulation: Final Rule Amending the Quality System Regulation
- Medical Devices; Laboratory Developed Tests
- Draft guidance on how to interpret 'significant change' of a medical devices: Overview
- List of Medical Devices - Notification of Shortages
- Proyecto de norma oficial mexicana PROY-NOM-137-SSA1-2024. Etiquetado de dispositivos médicos
- Brazilian Resolution RDC Nº 848/2024
- Brazilian Normative Instruction IN No. 290/2024
- Colombian Resolution No. 184/2024
- Chilean Decree No. 15 - Amending Decree no 41 exempt of 16 June 2022 of the Ministry of Health, which incorporates the IVD detection devices indicated to the sanitary control regime established in article 111 of the sanitary code.
- Mercosur technical regulation on essential safety and performance requirements for medical devices and in vitro diagnostic medical devices No. 7/2024
- IMDRF Guidance Regarding Information to be Included
- IMDRF Guidance on Principles of Labelling for Medical Devices and IVD - Edition 2
- IMDRF Guidance on Essential Principles of Safety and Performance of Medical Devices and IVD
- IMDRF Public Consultation on Medical Device Software - Considerations for Device and Risk Characterization

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