

Role of manufacturers in ensuring quality, safety & performance

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ANVISA

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Anvisa's Role



“Promote the **protection of the population’s health** by executing sanitary control of the production, marketing and use of products and services subject to health regulation, including related environments, processes, ingredients and technologies.”

Shared Responsibility



Manufacturers



Regulatory
Authorities



Medical
Devices

Medical Devices Regulatory Scheme



Legal Requirement

ANVISA RDC 665/2022

*“Article 4. Each manufacturer shall establish and maintain a quality system to **ensure that the products manufactured are safe, effective, and adequate for the intended use.**”*

Anvisa Data – Medical Devices

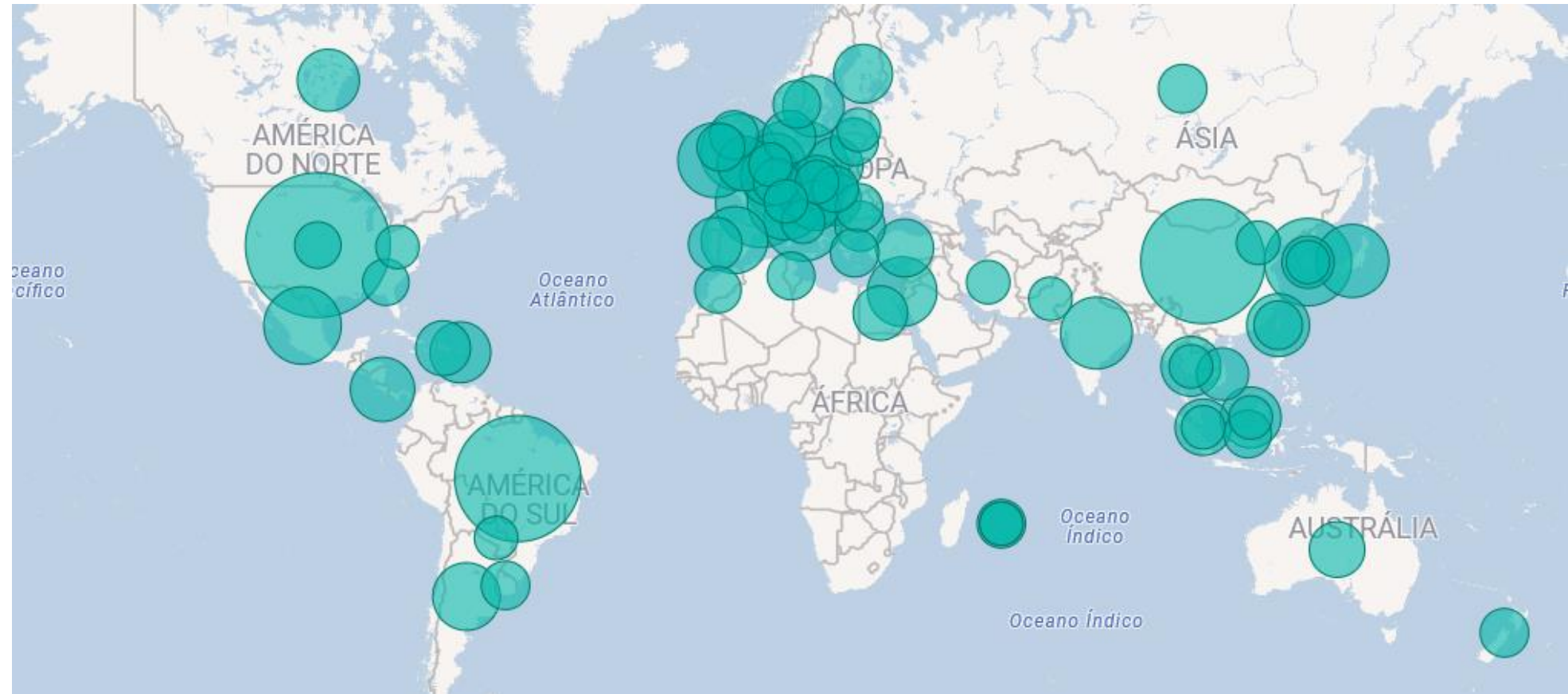


CBPF emitidos
GMP issued/CBPM emitidos
5494



Países
Countries/Paises
78

Active Licenses
of Medical Devices
87,758

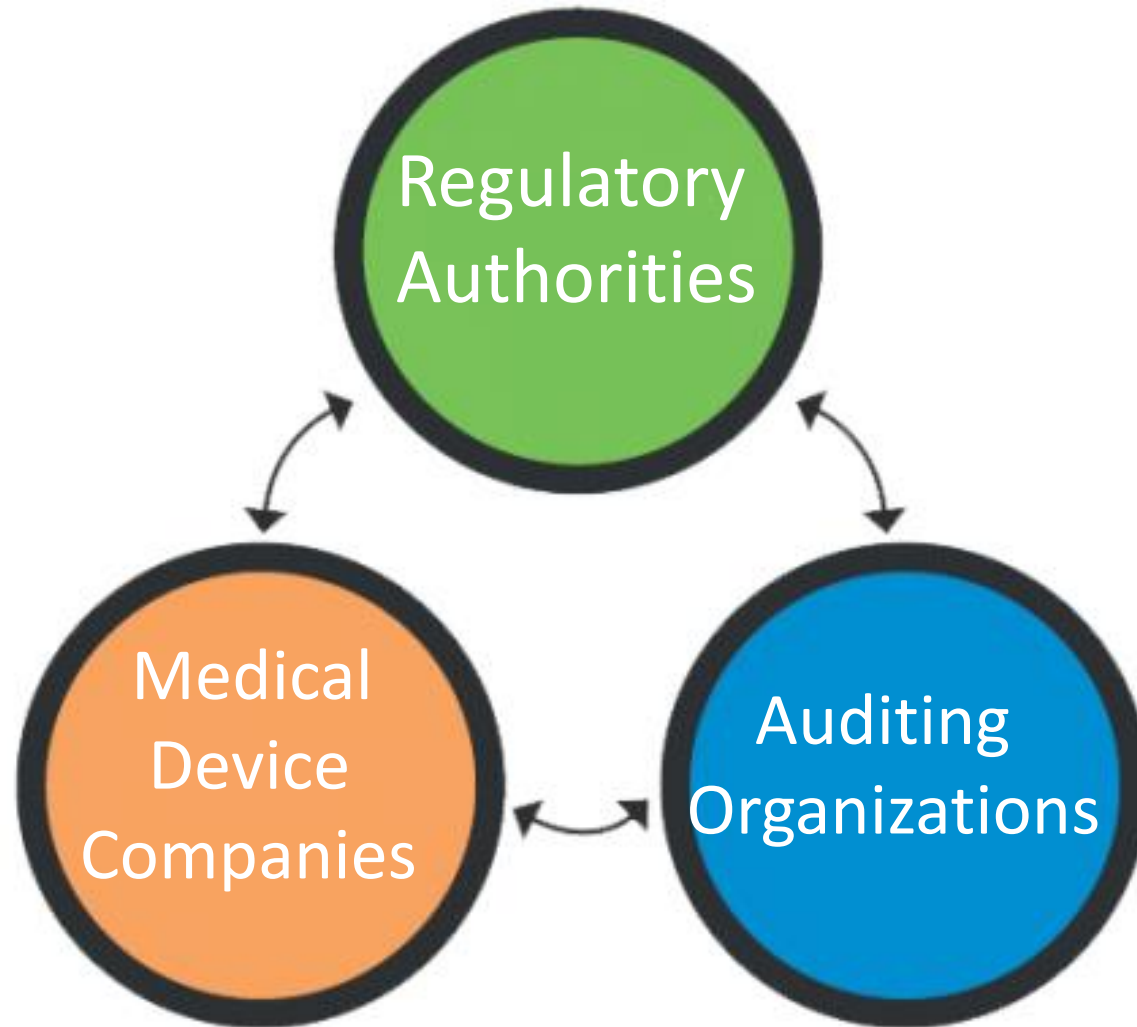


Lack of resources

- **Reliance**
- **Harmonization**
- **Regulatory Convergence**
- **Collaborative work**



Collaborative work



6938 Manufacturers

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

International Standard

ISO 13485 : 2016

*“Article 1. This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that **consistently meet customer and applicable regulatory requirements.**”*

ISO 13485 : 2016

Medical Device

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information by means of in vitro examination of specimens derived from the human body;

Medical devices used in the world per day

Billions?



Social Role

“Provide safe, effective, and adequate medical devices for the intended use to support or improve the quality of people’s life.”



