IMDRF International Medical Device Regulators Forum

Session 2
Reliance pathways and classification challenges.

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ANVISA

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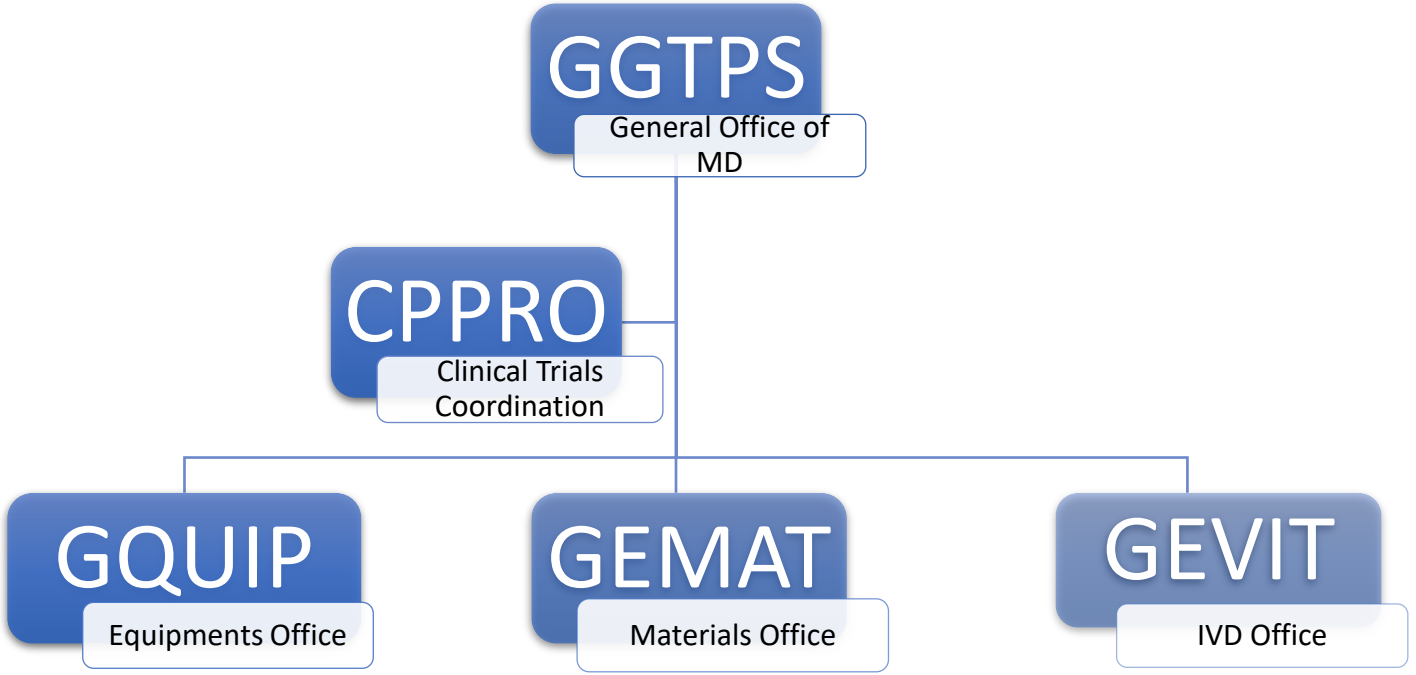
Brazilian Health Regulatory Agency
Anvisa

Criated by Law 9.782 of 1999, with a commitment to ensuring the safety, efficacy, and quality of health-related products and services.

Organization Chart
Medical Device General Office



General Office of Medical Devices

- Analysis of petitions for registration, notification, renewal, changes, and cancellation of Medical Devices.
- Determination of requirements for MD regularization.
- Provision of information on the status of regulated products.
- Guidance to the population and the regulated sector.
- Participation in international regulatory forums – Promotion of Regulatory Convergence

Number of MD Market Authorizations per Year in Brazil

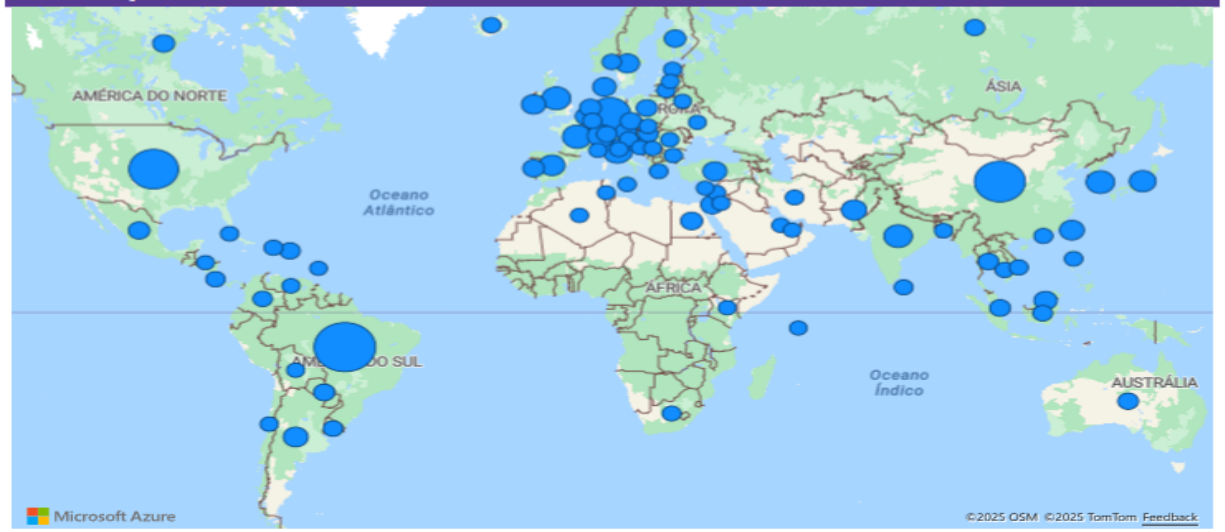
		2021	2022	2023	2024
Notification	Class I	3102	2718	2711	2797
	Class II	3443	3751	4162	4205
Registration	Class III	938	1014	718	921
	Class IV	254	328	300	393
Total		**7737**	**7811**	**7891**	**8320**

Origem

PAÍS FABRICANTE BRASIL QTD PRODUTOS	PERCENTUAL FABRICAÇÃO NACIONAL:	PERCENTUAL FABRICAÇÃO INTERNACIONAL:
30271	31,27%	68,73%

PAIS FABRICANTE	QTD PRODUTOS	PERCENTUAL
CHINA, REPÚBLICA POPULAR	17350	18,02%
ESTADOS UNIDOS DA AMÉRICA	15538	16,58%
ALEMANHA	8499	8,80%
ITÁLIA	2349	2,42%
FRANÇA	2120	2,19%
CORÉIA DO SUL	1839	1,90%
ÍNDIA	1818	1,90%
SUÍÇA	1621	1,70%
REINO UNIDO	1440	1,49%
JAPÃO	1263	1,32%
ESPANHA	1019	1,06%
PAQUISTÃO	920	0,95%
ARGENTINA	806	0,83%
TAIWAN	738	0,80%
IRLANDA	655	0,72%
TURQUIA	628	0,65%
SUÉCIA	598	0,62%
DINAMARCA	531	0,55%
ISRAEL	480	0,49%
MALÁSIA	461	0,48%
INGLATERRA (REINO UNIDO)	414	0,43%
EGITO	303	0,31%
CANADÁ	293	0,30%
BÉLGICA	288	0,30%
ÁUSTRIA	280	0,29%
HOLANDA (PAÍSES BAIXOS)	262	0,27%

DISTRIBUIÇÃO GEOGRÁFICA



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Total: 94.069
MD approved

Regulatory Convergence & Harmonization

Main motivations

- Converging to best international practices.
- Strengthen regulatory capacity globally and improve efficiency.
- Avoid duplication of efforts for regulators and industry.
- Harmonization of standards and technical requirements.
- Transparency and information sharing.
- **<u>Accelerate patient access to new technologies.</u>**

World Health Organization

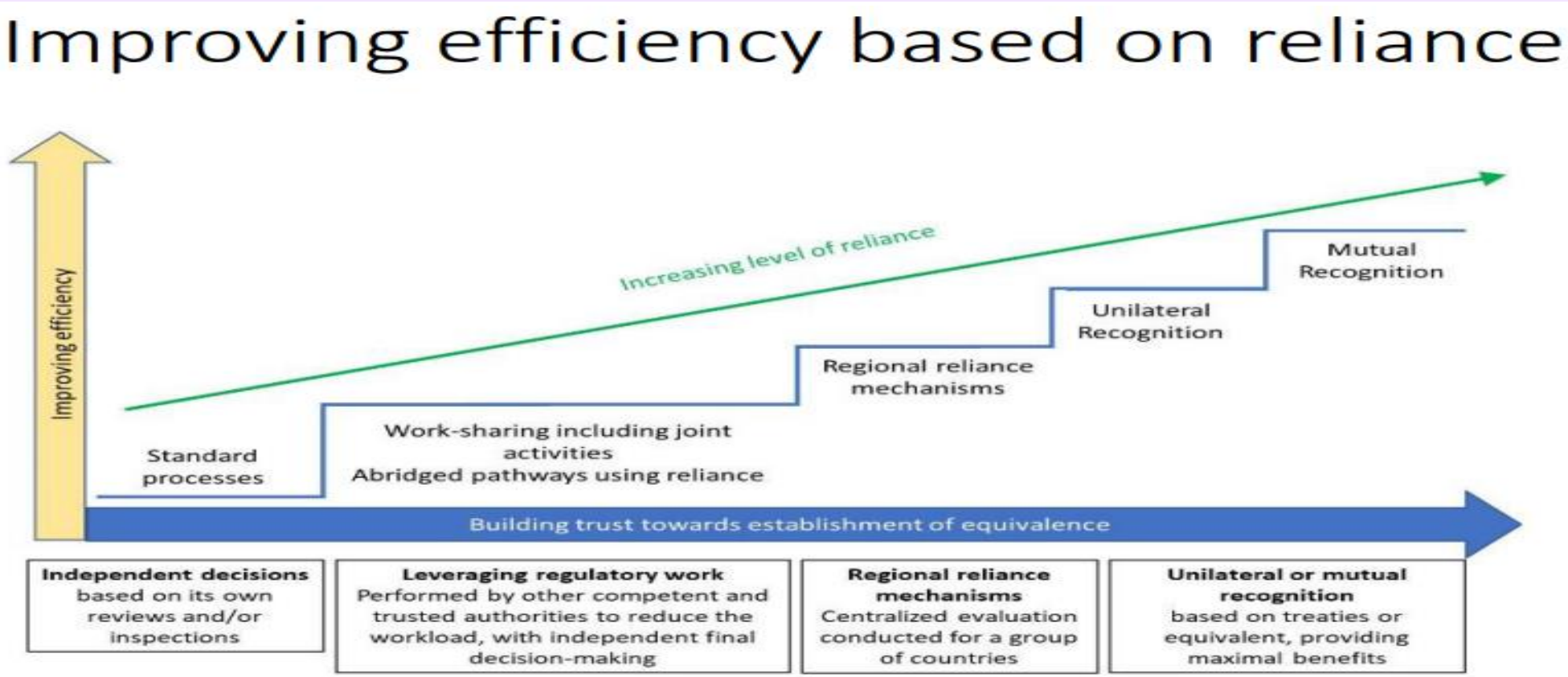
Bilateral Agreements

Reliance Definition

"The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others"

(WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 10)

Reliance Pathways



(WHO - Buenas prácticas de utilización de decisiones regulatorias de otras jurisdicciones en la regulación de productos médicos: principios y consideraciones de alto nivel, Anexo 10)

Reliance Regulation in ANVISA

- **RDC nº 741/2022 - General regulation on Reliance**

  Enabled abridged pathways for Pre-Market Authorizations.

- **IN nº 290/2024 - Reliance practices to non IVD and IVD – MD Pre-Market Authorizations,**

  Product registration certificates from Equivalent Foreign Regulatory Authorities (EFRAs, *AREE*s) may now be used for abbreviated analysis

- **AREE - MDSAP full members**
  - **Australia** Therapeutic Goods Administration (TGA) - Australian Register of Therapeutic Goods (ARTG)
  - Health **Canada** (HC) - Medical Device Licence
  - **USA** Food and Drug Administration (US FDA) - 510(k) Clearance, Premarket Approval (PMA), 513(f)(2) "De Novo"
  - **Japan** Ministry of Health, Labour and Welfare (MHLW) - Pre-market approval (Shonin)

Reliance Regulation in ANVISA

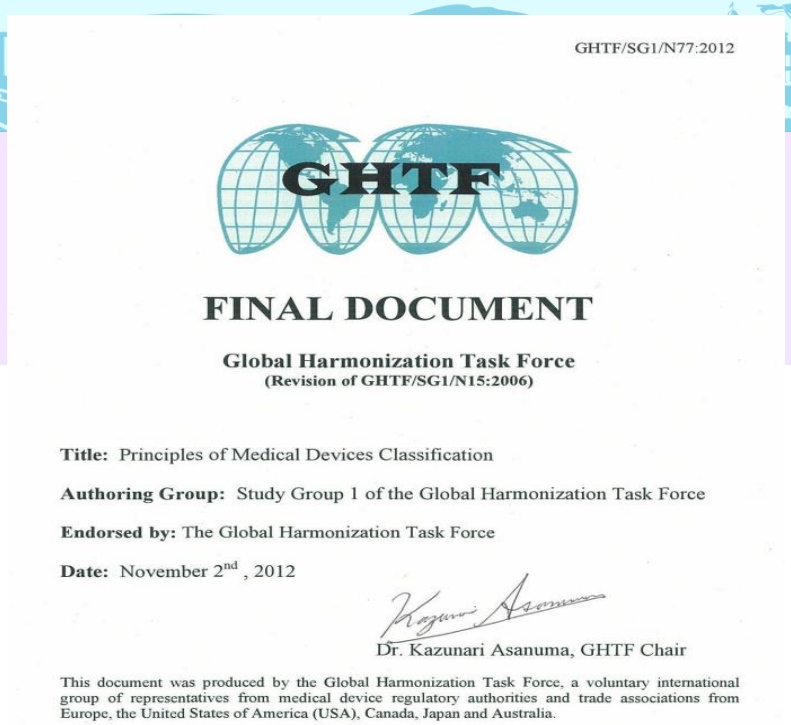
IN n. 290/2024

- **Class III and IV** Medical Devices (as defined on RDC 751/2022 and RDC 830/2023
- The product must be essentially identical:
  - *" the documentation that proves the registration or authorization issued by the AREE must refer to a medical device essentially identical to the one intended to be registered with Anvisa, and must include information regarding the indication(s) of use/intended use and manufacturer(s)“*
- Brazilian labeling and specific requirements must be met:
  - *The information shown in labels and instructions for use must be in Portuguese.*
  - *The DM that are subjects of compulsory certification must meet the requirements of specific regulations.*

⇨ Anvisa may choose, at any time, to carry out the full assessment of the tech dossier

Anvisa may ask for clarifications on the documents submitted for analysis

Risk Classification



GHTF/SG1/N77:2012

GHTF

FINAL DOCUMENT

Global Harmonization Task Force
(Revision of GHTF/SG1/N15:2006)

Title: Principles of Medical Devices Classification

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Endorsed by: The Global Harmonization Task Force

Date: November 2nd , 2012

Dr. Kazunari Asanuma, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

Product classification will help you establish requirements during the product development phase, specifically design control.

Classification is directly related to:

- **Intended Use** is the general purpose of the medical device or its function (what you "claim" the medical device does).
- **Indications for Use** describe the disease or condition the medical device will diagnose, treat, prevent, cure, or mitigate, including a description of the target patient population.

Risk Classification/ Regularization Schemes

GHTF/SG1/N77:2012 – Principles of Medical Devices Classification

Class	Level	Device Examples
A	Low Hazard	Bandages / tongue depressors
B	Low-moderate Hazard	Hypodermic Needles / suction equipment
C	Moderate-high Hazard	Lung ventilator / boné fixation plate
D	High Hazard	Heart valves / implantable defibrilator

Figure 1: Classification System for Medical Devices (Page 10/30).

Note: The examples of medical devices provided in Figure 1 are for illustration only and a manufacturer of such a device should not rely on it appearing as an example but should instead make an independent decision on classification taking account of its particular design and intended use.

Risk Classification/ Regularization Schemes

Risk Classification	Brazil	European Union	FDA
Risk Class	**I –** Notification **II –** Notification **III -** Registration **IV -** Registration	**I** - Self-certified **IIa** - Notified Body **IIb** - Notified Body **III** - Notified Body	**I -** General Controls **II -** Premarket notification requirements - 510(k) sbmission **III -** Premarket Approval (PMA)
Classification Rules	**Rules 1 through 4 cover non-invasive devices.** **Rules 5 through 8 cover invasive devices.** **Rules 9 through 13 cover active devices.** **Rules 14 through 22 are special rules covering devices that do not fall into the first three categories, such as nanomaterials.**		Considering the intended use and indications for use, the device must comply with the definition of a classification regulation – general categories based on the medical speciality in the **CRF (Code of Federal Regulations) Title 21 – Food and Drugs: Parts 862 to 892.**

Regulatory Convergence

Resolution for **risk classification**, notification and registration regimes, labeling requirements and instructions for use of non IVD medical devices and IVD medical devices:

- **RDC ANVISA Nº 830/2022**
  - IMDRF/RPS WG/N64 FINAL:2021 – Principles of In Vitro Diagnostic (IVD) Medical Devices Classification.
  - IMDRF/ /RPS WG/N13 (Edition 3) FINAL:2019 – In Vitro Diagnostic Device Market Authorization Table of Contents (IVD MA ToC).

- **RDC ANVISA Nº 751/2022**
  - GHTF/SG1/N77:2012 – Principles of Medical Devices Classification.
  - IMDRF/RPS WG/N9 (Edition 3) FINAL:2019 - Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC).

- **RDC ANVISA Nº 848/2024**
  - IMDRF/GRRP WG/N47 FINAL:2024 – Essencial Principles of Safety and Performance of Medical Devices and IVD Medical devices.

Risk Classification

Class I
Low Risk

Class II
Medium Risk

Class III
High Risk

Class IV
Max. Risk

"*NOTIFICATION*"
(Simplified premarket approval)

- Notification form
- Graphic images
- Manufacturer's declaration/authorization
- The Technical Dossier does not need to be submitted with the notification request but must be available and maintained by the holder of the notification for when it is requested

- Indefinite validity.

"*REGISTRATION*"
(Complete premarket approval)

- Registration Form
- Product Model Spreadsheet
- Instructions for Use
- Labeling
- Technical Dossier
- Certificate of Legal Marketing Auth. – CLC
- GMP Certificate
- Certificate of Conformity

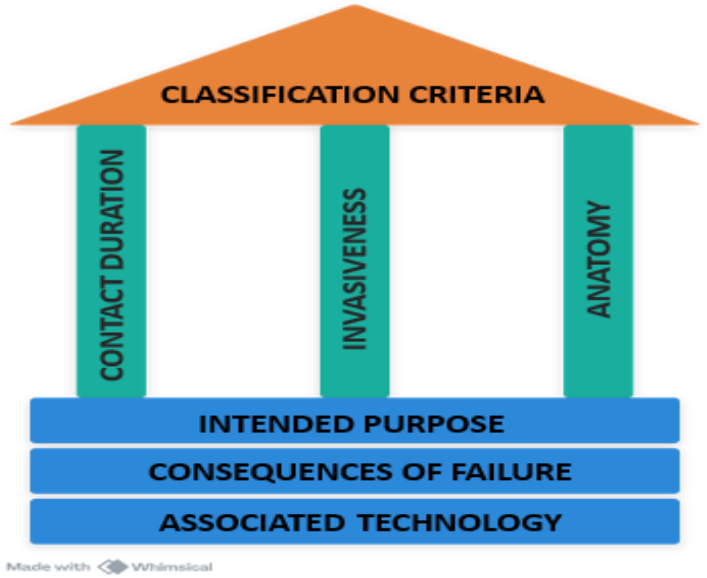
- Must be revalidated according to RDC nº 250/2004. (10 Years)

Changes are subject to approval, categorized as:

- Approval-required changes
- Immediate implementation changes
- Non-reportable changes

Risk Classification Rules

RDC nº 751/2022 – Non IVD Medical Device



Medical devices are classified according to the intrinsic risk they may pose to the health of the consumer, patient, operator, or third parties, into **Classes I, II, III, or IV.**

Risk Classification

RDC nº 751/2022 – Non IVD Medical Device

Product family (RDC n° 556/2021):

- Grouping of healthcare materials that may belong to the same registration or notification and that follow established general criteria such as: belonging to the same manufacturing group, having the same operating principle, mechanism of action, indication for use, contraindication, adverse effect, precaution, restriction, warning, special care, storage conditions, and risk class, as well as having similar raw materials and manufacturing technology.
- Examples:
  - Central venous catheters 1, 2, or 3 lumen .
  - Single, double, triple, or quadruple blood bags.
  - Surgical sutures with diameters of 1-0, 2-0, and 3-0.
  - Textured breast implants with volumes of 200, 220, 240, and 260 mL.

  - **The product registration covers only one type of product, which may vary in terms of design, dimensions, substance concentration, among other factors.**

Risk Classification

RDC nº 751/2022 – Non IVD Medical Device

Kit, Set (RDC n° 556/2021):

- A group of healthcare materials from the same manufacturer or manufacturing group, used in a specific procedure and which, individually, are not interdependent in order to achieve their intended functionality and performance.
- Examples:
  - Hemodialysis Catheter Kit: consisting of a hemodialysis catheter, scalpel, dilator, introducer needle, guide wire, injection cap, and introducer needle.
  - Dressing Kit: consisting of gauze, bandage, scalpel, scissors, tweezers and adhesive tape.
  - Epidural Anesthesia Set: consisting of an epidural needle, catheter, syringe, surgical drape, antiseptic sponges, basin, gauze pad, and surgical drape.

  - **For kit, set or tray the regulation covers different types of products that are intended for a specific procedure. However, the individual functionality of each component of the set in the procedure is independent.**

Risk Classification

RDC nº 751/2022 – Non IVD Medical Device

System: (RDC n° 556/2021):

- A product from the same manufacturer or group of manufacturers, consisting of complementary and compatible components for **exclusive use with each other**, for a single and specific function, which are interdependent to achieve functionality, intended for a specific procedure and whose **performance is only achieved if used in an integrated manner**.
- Examples:
  - Nebulization system: consisting of a nebulization mask, reservoir cup, cap, and trachea.
  - Mediastinal drainage system: consisting of a catheter/drain, extension tube, collection bottle, connector, and flow-blocking clamp.

  - **In the case of systems, the regulation also covers different types of products; however, the individual functionality of each component is interdependent to achieve functionality in the procedure for which it is intended.**

Risk Classification

RDC nº 751/2022 – Non IVD Medical Device - Rule 11, SaMD RDC nº 657/2022

- Software intended to provide information used for therapeutic or diagnostic decision-making is classified in **class II**, unless such decisions have an impact that could cause:
  - serious deterioration of a person's health or surgical intervention - **class III;**
  - death or irreversible deterioration of a person's health - **class IV.**
- Software intended to monitor physiological processes is classified as class II, except when intended to monitor vital physiological parameters, where the nature of the variations in these parameters could result in immediate danger to the patient, in which case it is classified as **class III**.
- Any other Software as a Medical Device (SaMD) is classified as **class I**.

Risk Classification

IVD – RDC nº 830/2023

- The application of classification rules is governed by the **intended purpose** of in vitro diagnostic medical devices:

  - If the device is intended to be used in combination with another device, the classification rules apply separately to each device.
  - The applicant must take all rules into consideration in order to establish the correct classification of the product.
  - If the manufacturer declares that a device has multiple intended purposes and is therefore covered by more than one class, the device is classified in the higher risk class.
  - If several classification rules apply to the same device, the rule that leads to the highest classification applies.

Risk Classification

IVD – RDC nº 830/2023

- **Class I:** low risk to the individual and low risk to public health;
  - Instrument for sample preparation and processing.
  - Dyes, sample collectors, diluents, buffers, lysis solutions.

- **Class II:** medium risk to the individual and/or low risk to public health;
  - Instrument that will generate results on the sample.
  - self-tests (fertility, pregnancy, vaginal pH, etc.); drugs of abuse (cocaine, THC, etc.); some therapeutic drugs (kanamycin, tobramycin), hormones (testosterone, prolactin), biochemistry (iron, calcium, vitamins), allergens, some microorganisms (giardia, helicobacter pylori, legionella).
  - **All parameters that do not fit into other classes.**

- **Class III**: high risk to the individual and/or medium risk to public health;
  - COVID-19 - initially, it was prohibited as a self-test, but later it was approved as a Class III device.
  - DENGUE – requires mandatory notification to the Brazilian Ministry of Health due to epidemiological factors.

- **Class IV**: high risk to the individual and high risk to public health.
  - HIV - A false negative result can dramatically delay treatment, increase the chance of transmission, and have serious individual and public health consequences.
  - HPV (DNA/RNA) results are used for primary screening of cervical cancer, impacting critical decisions (need for colposcopy and biopsy)

✓ **The risk classification takes into account the country's risk perception, impact on public health, epidemiological context, need for counseling and monitoring by a healthcare professional and regulatory framework.**

Risk Classification

IVD – RDC nº 830/2023

- Products that **cannot be classified as self-tests** and, therefore, cannot be supplied to lay users, are those that have the following purposes:
  - testing samples to verify the presence of or exposure to pathogenic organisms or transmissible agents, including agents that cause infectious diseases subject to compulsory notification;
  - performing blood typing;
  - performing genetic tests to determine the presence of or predict susceptibility to disease or physiological conditions;
  - assisting in the diagnosis or indicating the presence of disease, cardiac or tumor markers, or conditions with serious health implications; and
  - indicating the presence of drugs or their metabolites.

✓ **The prohibition on supplying lay users may be waived by Resolution of the Collegiate Board, as a result of a request received from the Brazilian Ministry of Health.**

✓ **The prohibition does not apply to devices intended for the detection of the presence of or exposure to an agent causing genital infection, provided that it is not classified as a notifiable disease, according to Brazilian Ministry of Health.**

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https://www.gov.br/anvisa/pt-br

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Agência Nacional de Vigilância Sanitária