VERA ROSAS
GROUP

FIME

ORLANDO, USA - JULY 2018

PRESENTATION TOPICS

- WHAT IS VERA ROSAS GROUP?
- IMPORTANT INFORMATION ABOUT BRAZIL
- INTRODUCTION ABOUT ANVISA
- BRAZILIAN REGULATORY AFFAIRS OVERVIEW (CLASSIFICATION, MODALITIES OF PROCESSES, CERTIFICATIONS REQUIRED AND TIMEFRAMES)
- POST REGISTRATION ACTIONS
- TENDENCIES
- FAQ

WHO WE ARE

Founded in 1999 by Vera Rosas, the Group has 4 companies, with the Headquarter located in São Paulo.

VERA ROSAS
Regulatory Affairs

Consultancy company specialized in product registration, company legalization, pre-inspections, inspections, to help companies to obtain Certification of Good Manufacturing Practices required by ANVISA.

VR MEDICAL
Importadora e Distribuidora

Brazilian registration holder for Medical, Cosmetic and Sanitizing Products. Company dully licensed before Brazilian Health Authorities and provides technical and operational support to international companies seeking to operate in the Brazilian market.

BIODEVICES

It is an importer and manufacturer prepared to assist small and medium-sized companies by offering solutions regarding manufacturing*, import, nationalization, storage and distribution of the Health Products and Cosmetics.

VLR REGULATORY AFFAIRS

Satellite office located in the United States to deliver technical and operational support to International companies targeting the Brazilian market.

Manufacturing (class I and II products)*

VERA ROSAS GROUP

Technical Team:

- Pharmacists and Biomedical Professionals with more than 10 years of experience, highly qualified and committed team to meet the most diverse needs of national and international clients.

Expertise Areas:

- Health Products (Consumables, Equipment, Implantable, IVD), Food, Sanitizing and Cosmetic Products.

Our Results:

- Brazilian Regulatory Consultancy Company with the highest number of products approved at ANVISA (More than 2.000 products approved by VR Medical – registration holder).
- More than 20.000 processes submitted at ANVISA.
- 98% approval rate.

Our Clients:

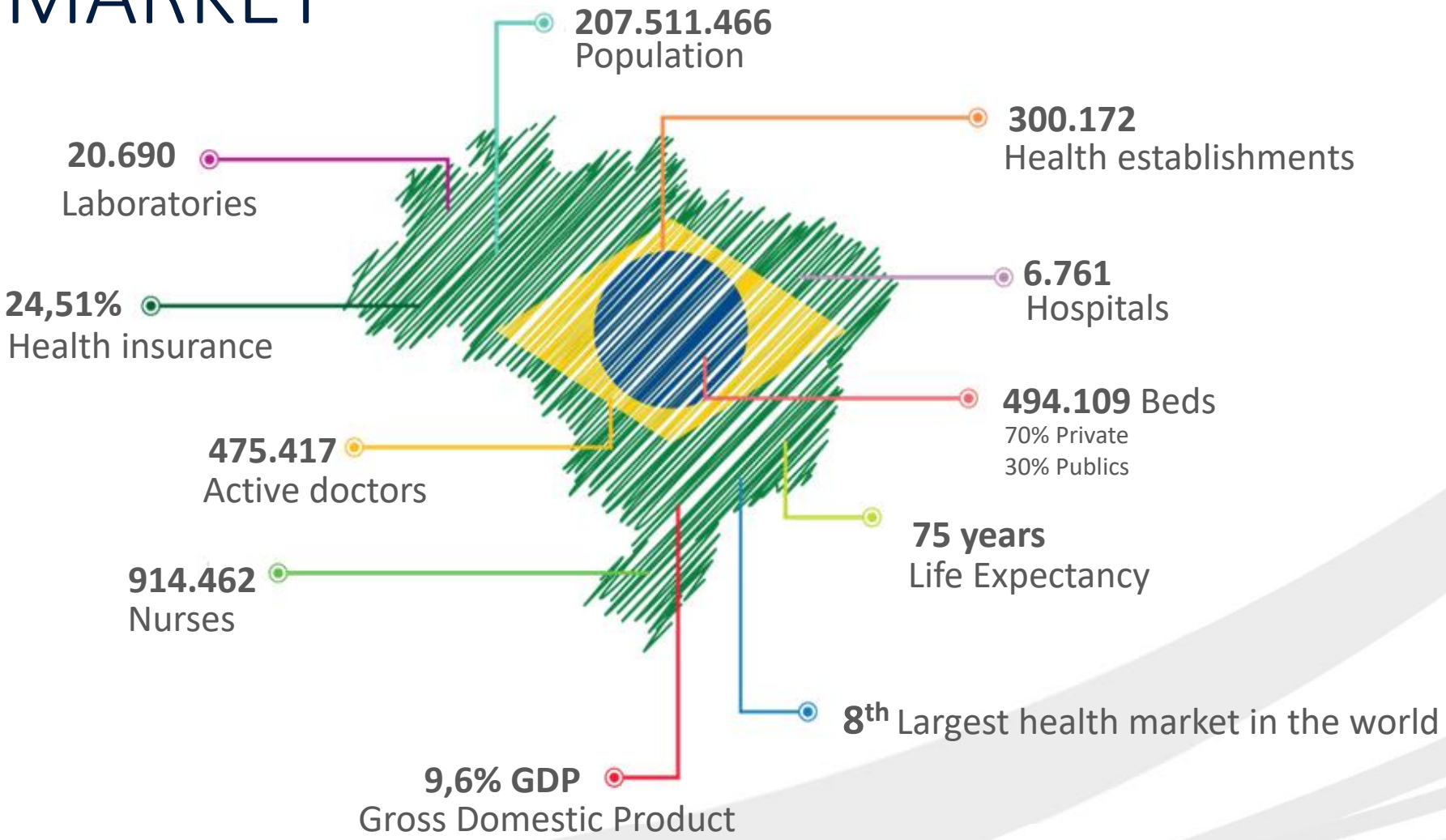
- 43% Manufactures
- 57% Importers

ABOUT BRAZIL

Do you know how big Brazil is?

- **5th** largest country in the world
- Largest market in Latin America
- One of the TOP 10 largest economies in the world

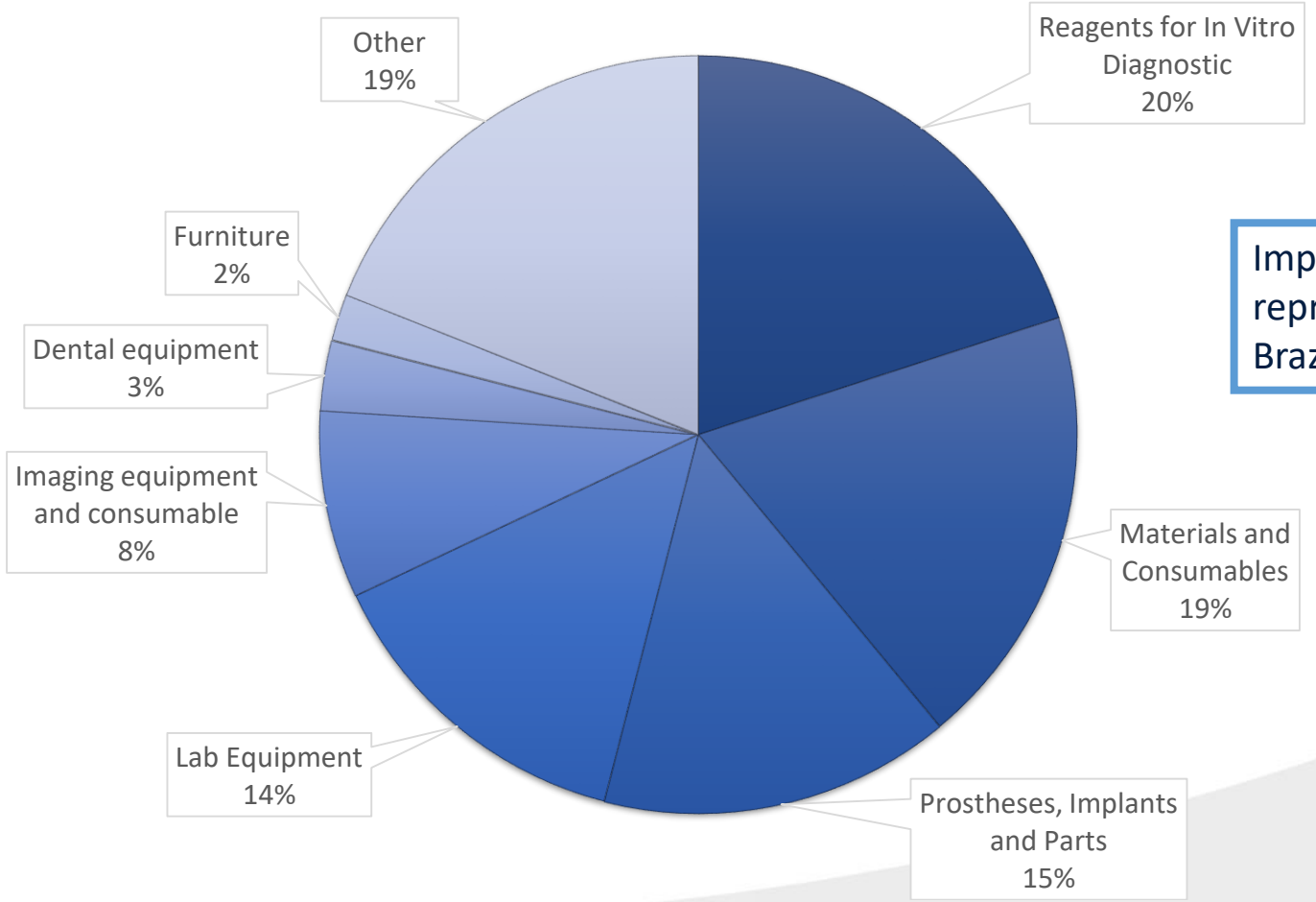
HEALTH MARKET



Source: http://www.hospitalar.com/pt/o-evento/setor-da-saude

BRAZILIAN HEALTH MARKET

Segmentation of the market for medical equipment and devices



Implants and medical equipment represent almost 50% of the Brazilian revenue.

Source: https://www.export.gov/article?id=Brazil-Healthcare

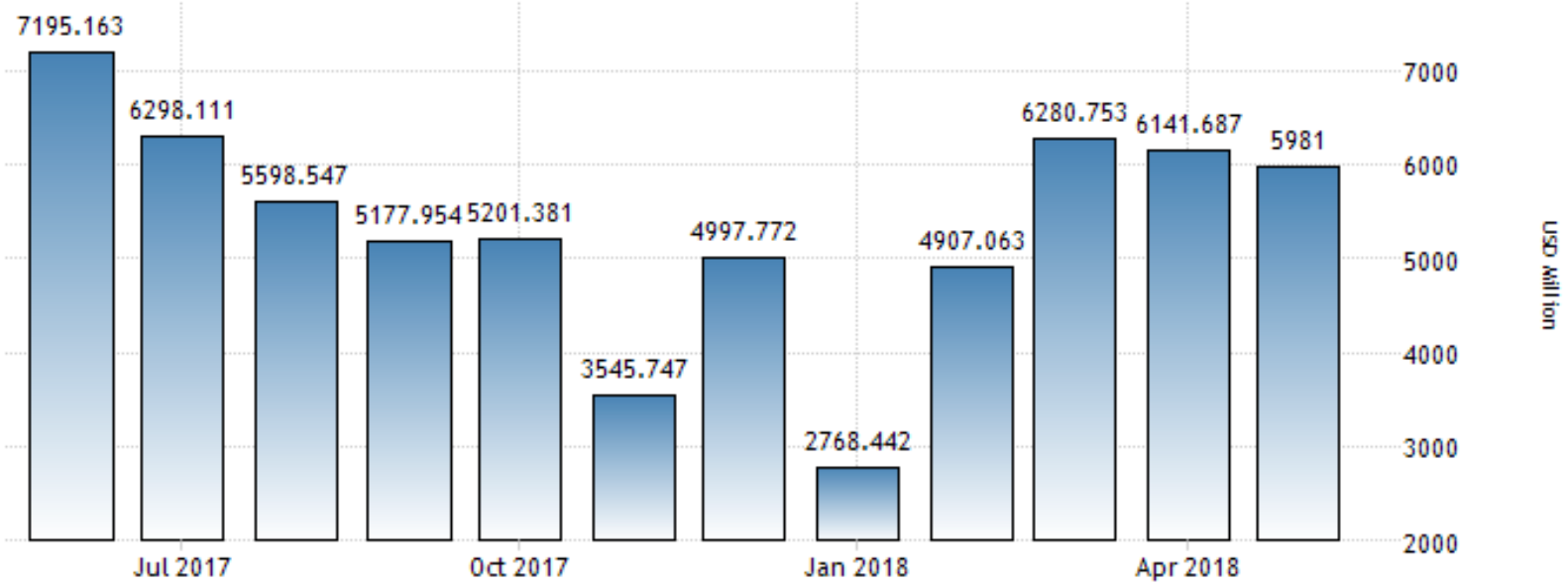
BRAZILIAN MAIN PARTNERS

Jan-May 2018

Country	Imports	Exports
China	24.132.277.012	12.365.476.257
USA	10.442.899.627	11.416.003.835
Germany	2.155.070.699	4.300.930.286
Japan	1.815.600.336	1.780.460.767

Source: http://www.mdic.gov.br

BRAZILIAN TRADE BALANCE



Source: https://tradingeconomics.com/brazil

Brazilian Regulatory Affairs and Medical Devices Registration

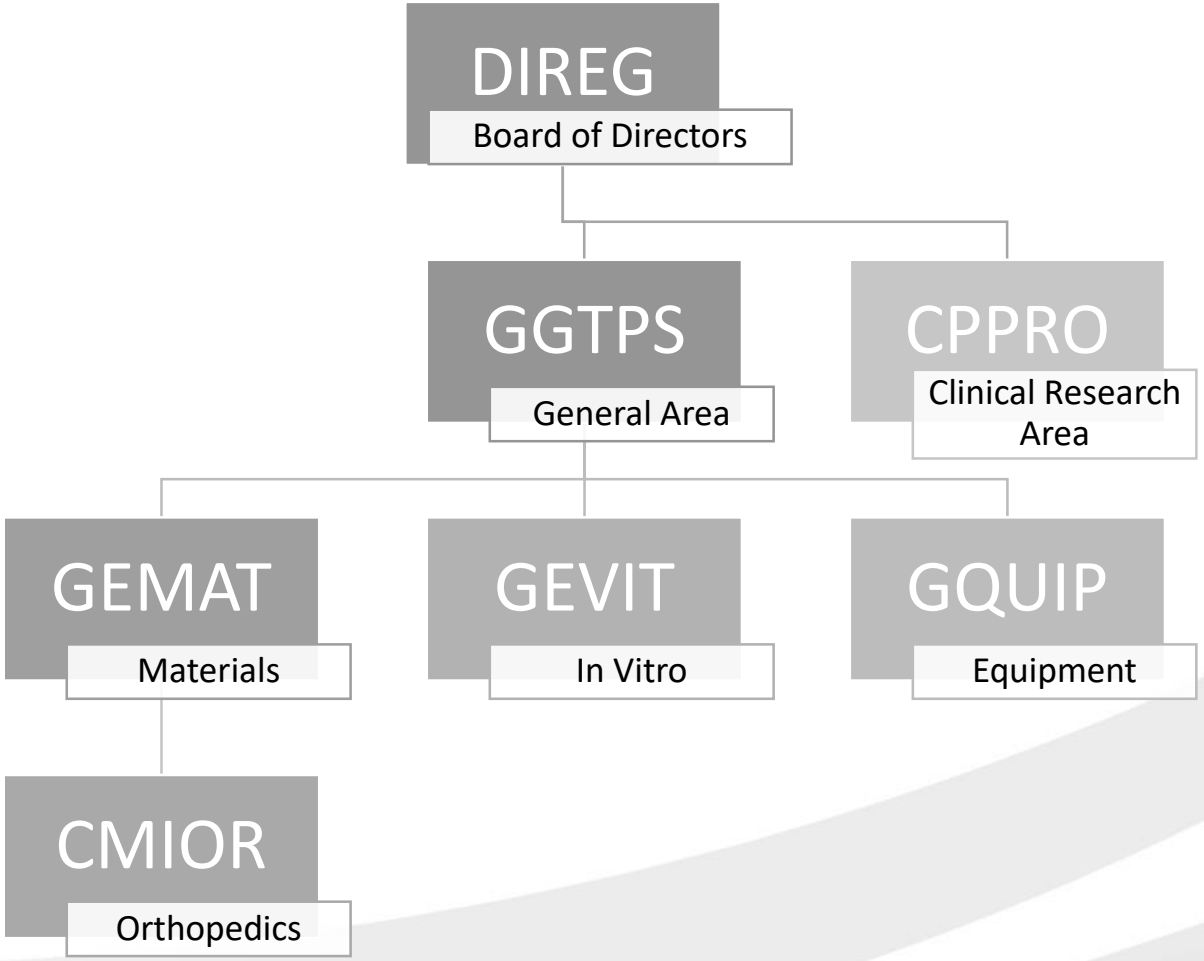
WHAT IS ANVISA?

- Brazilian National Health Surveillance Agency (located in Brasília)
- Protects and promotes public health, by exercising health surveillance over products and services
- Health control of ports, airports and borders
- Administrative independence and financial autonomy
- Subject to the Ministry of Health, Ministry of International Affairs

  and with foreign agencies and institutions

Website: http://portal.anvisa.gov.br

ANVISA DIVISIONS (Health Products)



HOW TO START?

1st step = Find a local registration holder

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1st step = Find a local registration holder

Ways to have a local registration holder

OPENING A SUBSIDIARY IN BRAZIL

HIGH INVESTMENT

AT LEAST 1 YEAR FOR LICENSING

INDEPENDENCE

FINDING A DULY LICENSED LOCAL DISTRIBUTOR

DISTRIBUTOR OWNS THE REGISTRATION

REQUIRES EXTENSIVE RESEARCH AND NEGOTIATION WITH THE PARTNER

MARRIAGE

WORKING WITH THE HOSTING ALTERNATIVE

POSSIBILITY TO EXPLORE BRAZILIAN MARKET

MANY DISTRIBUTORS

MANUFACTURER OWNS THE REGISTRATION

FREEDOM

MAIN RESPONSIBILITIES

Hosting Company = Legal Representative

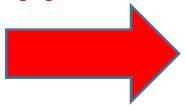
- Maintenance of the sanitary permits
- Maintenance of qualified staff to meet the manufacturer needs
- Product liability towards consumer protection agencies, governmental and private entities, INMETRO
- Civil and criminal liability regarding the products
- Qualification of the distributors (documental inspection) and manufacturers
- Inform ANVISA about technical complaints and adverse events related to the product (Technovigilance)
- Answering questions about technical surveillance issued by ANVISA
- Support and coordination of Recall processes
- Support distributors regarding the labeling of imported products
- Control of the import authorizations to ensure traceability

INITIAL CONSIDERATIONS

The product risk classes

2nd step = Classification of the device

All classes require ANVISA approval



ANVISA	CE Mark	FDA
I	I	I
II	IIa	II
III	IIb	III
IV	III	

Comparison between the classification, in terms of risk, for Medical Devices (ANVISA x CE Mark x FDA):

Definition of medical product according to RDC 185/2001: *Product for health, such as an equipment, device, material, article or system of medical, odontological, or laboratory use/application, intended for the prevention, diagnostic, treatment, re-habilitation or anticonception, that does not use pharmacological, immunological or metabolic means, to perform its main function in human beings, that may be helped in its functions by such means.*

BRAZILIAN PRODUCT

Classification

- **Class I – LOW RISK**

Non-invasive products, temporary use (up to 1 hour)

- **Class II – MEDIUM RISK**

Invasive products, short term use (up to 30 days)

- **Class III – HIGH RISK**

Surgical products, long term use (over 30 days)

- **Class IV – MAXIMUM RISK**

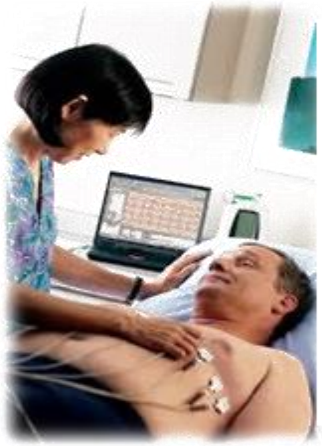
Permanent implants and surgical products for long term use with direct contact with the Central Nervous System, Coronary System or biologically absorbed

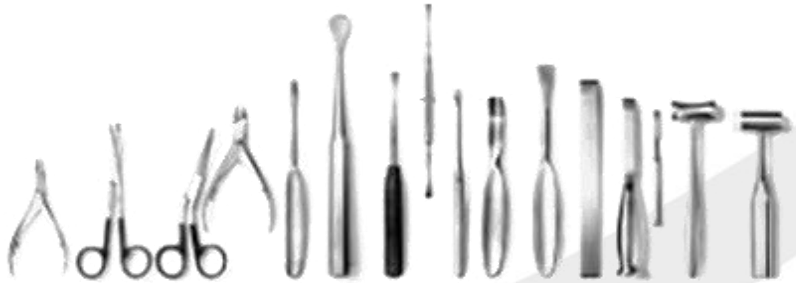
Related law: RDC 185/2001

EXAMPLES OF PRODUCTS

Risk Class I and II

- Surgical Instruments and sterilization trays
- Surgical clothing (aprons, masks, etc)
- Pregnancy rapid tests (IVD)*
- Most of the dental products
- Catheters for periphery use
- Surgical beds and tables
- Equipment for diagnostics (IVD)*
- ECGs
- Ultrasounds
- Ophthalmologic equipment (slit lamps, tonometers, etc)
- Software (PACs)





** IVD products has specific regulation*

EXAMPLES OF PRODUCTS

Risk Class III and IV

- Implantable products (dental, orthopedic prosthesis, etc)
- Stents
- Intra ocular lenses
- Glucose Meter and Consumables (IVD)*
- Bone graft, bone cements
- Products impregnated with drugs
- X-ray, laser and high frequency equipment
- Ventilators
- Multiparameter monitors
- Condoms
- Software for radiotherapy dosage

** IVD products has specific regulation*

EXAMPLES OF PRODUCTS

With specific legislation

- Cosmetic products (creams, repellents, shampoos, etc) *
- Pharmaceutical products *
- Sanitizing products (disinfectants, detergent, etc) *
- IVD (reagents, kits, biomarkers, instruments, etc)
- Blood Bags and some diagnostic reagents as HIV/ Syphilis (Typing Test is pre required for registration)




**Important: For the classification of these kind of products a previous analysis of the formula is needed.*

EXAMPLES OF PRODUCTS

Don’t need ANVISA approval

- Raw material for medical products (plastics, metals, etc)
- Anatomical models for training/ education
- Products exclusively for laboratory use, except for *in vitro* diagnostics (water analyzer, laboratory heater, pipette, bucket)

MAIN DIFFERENCES

Related to the risk classes

	I and II	III and IV
Modality of process	**Notification / Enrollment**	**Registration**
Specific documents	**Authorization Letter and technical dossier (RDC 40/2015)**	**CFG/CFS, authorization letter and documents proving safety and efficacy (RDC 185/2001)**
INMETRO / ANATEL Certifications	**May be required**	**May be required**
GMP Certification (Good Manufacturing Practices certification issued by ANVISA for the manufacturer facility)	**Not applicable**	**Mandatory**
Expiration	**Undetermined**	**10 years**

GMP CERTIFICATION

Class III and IV Products

	Until October 2017	New Regulation
GMP Inspection	GMP Inspection performed by ANVISA, according to the RDC 16/2013	ANVISA will define the necessity of inspection based on a risk analysis of the manufacturer's documentation RDC 183/2017
		ANVISA GMP Inspection can be replaced by: * Inspection performed by other agencies/certification bodies (MDSAP, IMDRF, CMDCAS or Sanitary Authority of the Country of Origin)
Timeline	3 - 4 years	Currently: 2 years / ANVISA goal: 6 months
ANVISA Fee	Mandatory	
Certificate Expiration	2 years	
Important Considerations	GMP x product registration (run in parallel). ABIMED members are allowed to have the registration approved based on the GMP submission only. If the GMP is denied, the company may have the registrations cancelled and/or the products recalled. GMP Certificate belongs to the Brazilian registration holder.	

MANDATORY CERTIFICATIONS

INMETRO

- National Institute of Metrology, Standardization and Industrial Quality.
- Goal: assure the safety and quality of the products through tests to evaluate the product and then issue a certificate of conformity by a Brazilian Certification Body.
- Applicable for specific products, example:




- Certificate valid for 5 years.
- Pre requirement for registration!

NEW

MANDATORY CERTIFICATIONS

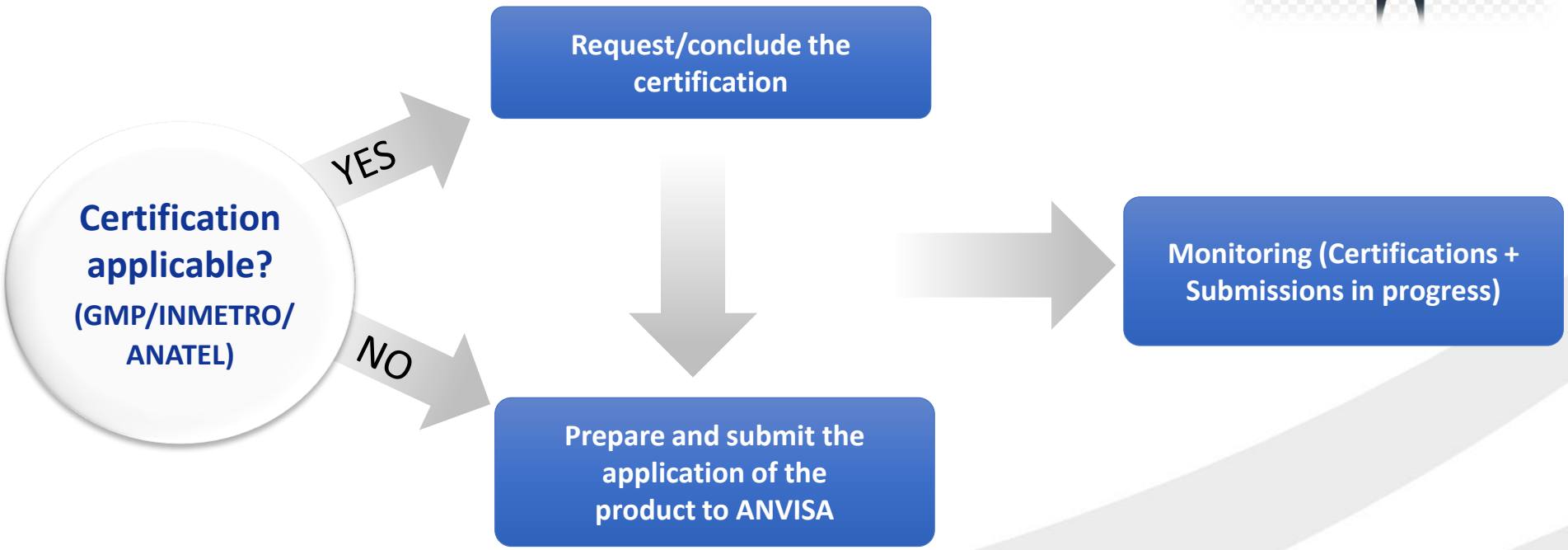
ANATEL

National Telecommunications Agency

- Resolution nº 680/2017 : all devices that incorporate telecommunications modules, such as wireless communication or that work connected to the telephone (eg. bluetooth, wifi, cellphone interface) require ANATEL certification.
- ANVISA requires Homologation Certificate to approval and maintenance of registration processes.
- Certificate expiration depends on the characteristic of product (Between 1 - 2 years or undetermined).
- Pre requirement for registration!

SUBMISSION FLOW SUMMARY

Application overview



ANVISA APPROVAL TIME SUMMARY

Estimatives

RISK CLASS	TIMEFRAME
I and II	2 - 4 months
III and IV (Predicate/ Similar Devices and Equipment)	3 - 6 months
III and IV (Implantable, Innovative Products, Drug incorporated, etc.)	8 - 12 months
Registration Changes	Around 3 months

IMPORTANT CONSIDERATIONS

Particularities of Brazil

- All approvals are published in the Brazil's Official Gazette
- No approvals by similarity: predicate/similar devices previously approved don't avoid a new submission
- Safety and efficacy data by similarity is critically analyzed by ANVISA
- FDA approval is very positive in case of products class III, IV and innovative products
- A Clinical Research in human beings at least phase III is mandatory to Implantable and Innovative Products
- NEW UDI (Unique Device Identification) will be mandatory to coronary and pharmacological stents, hip and Knee Implants (From 2020 on)
- Different technicians from ANVISA can make different requests

POST REGISTRATION ACTIONS

- Updates/changes related to the products usually require ANVISA approval before the implementation

- Product registrations must be renewed each **10 years,** GMP Certification each **2 years** (deadline: 6 months before expiration date) and INMETRO certification each **5 years**

- Class I and II submissions do not require renewal, although the INMETRO/ANATEL certificates must be valid as a condition to maintain the ANVISA approval active

- Technovigilance events and Field actions require notifications according to specific regulations

- Transfer of registrations and GMP Certification between companies is allowed

TENDENCIES

- Simplified online submission for products class I (Public Consult is on going)
- Specific regulation for Customized Products
- Harmonization ANVISA x other countries (IMDRF - International Medical Device Regulators Forum - http://www.imdrf.org/)

UPCOMING EVENTS

Meet our team

- **RAPS 2018** (Canada) > October, 01 - 04
- **Medica 2018** (Germany) > November, 12 - 15

Thank you!

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