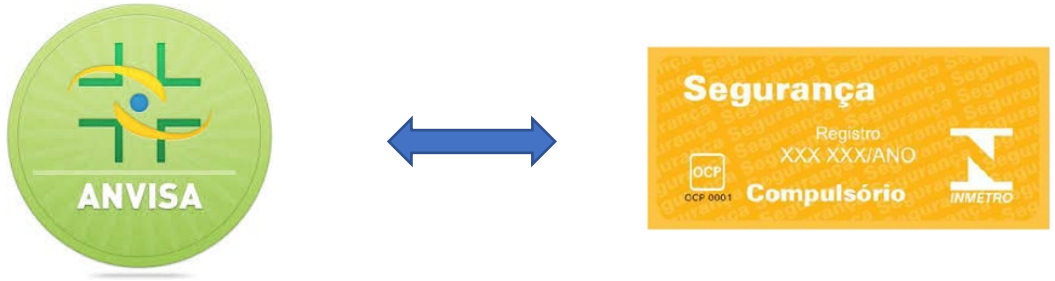
Workshop ANVISA-INMETRO-USFDA-NIST - Medical Device Conformity Assessment

Conformity Assessment for Medical Devices



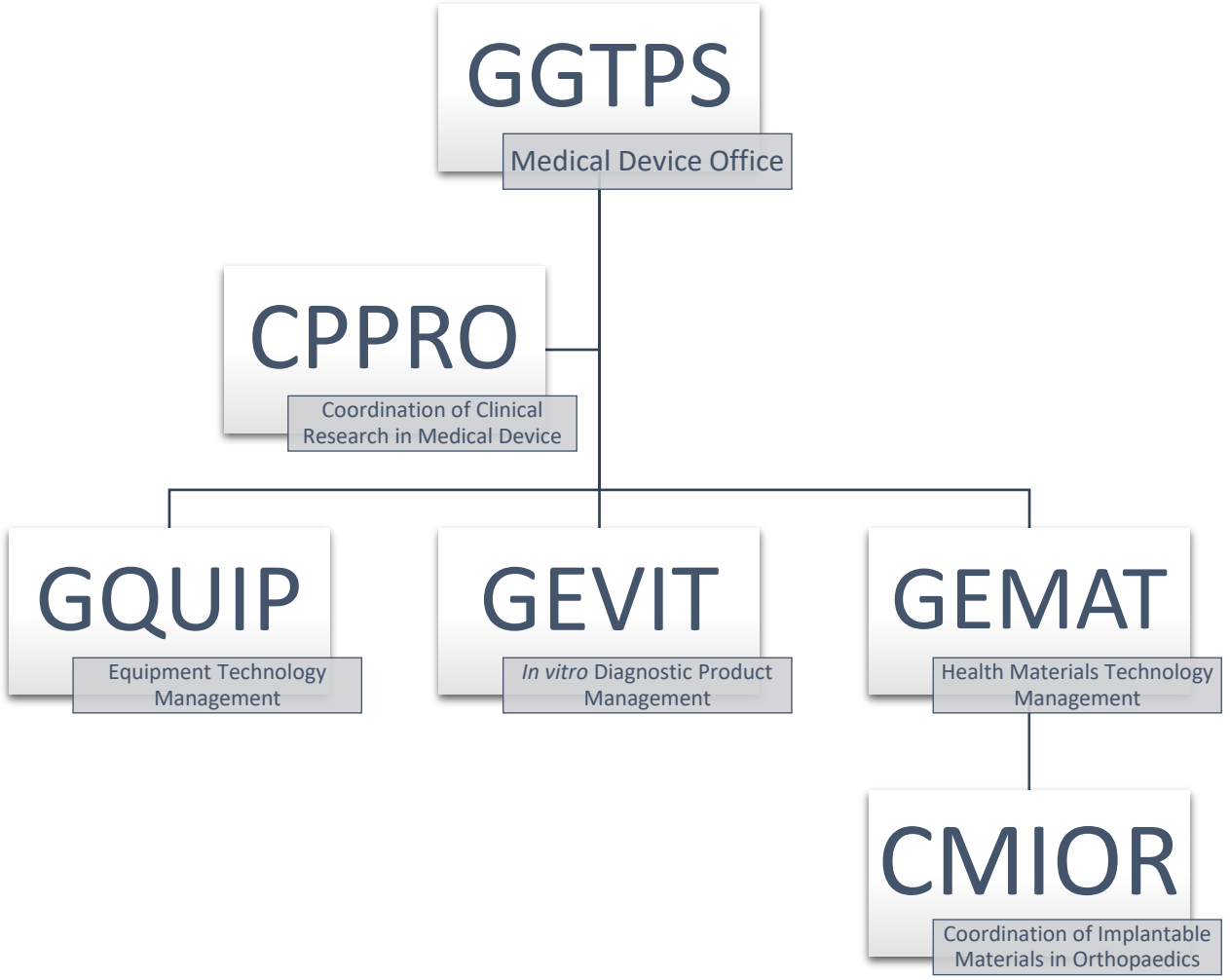
Brazilian Health Regulatory Agency

Medical Devices Office - GGTPS

10/24/2023

Brasília, DF, Brazil

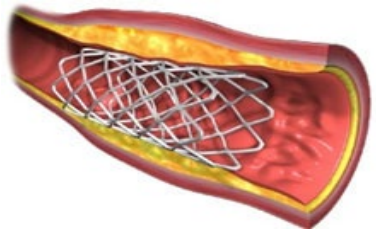
ORGANIZATIONAL CHART OF THE MEDICAL DEVICES AREA

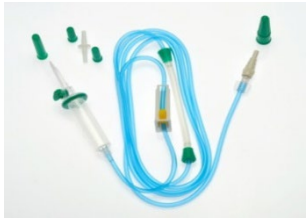
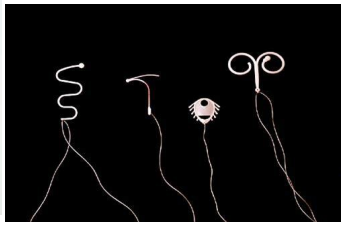


IN VITRO DIAGNOSTIC PRODUCT MANAGEMENT - GEVIT

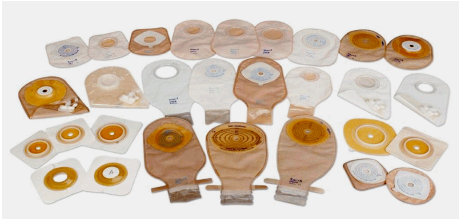
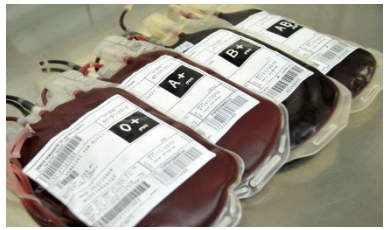
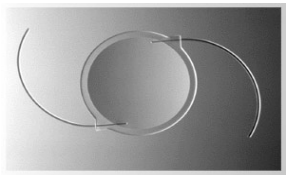
Health Materials Technology Management - GEMAT
Coordination of Implantable Materials in Orthopaedics - CMIOR





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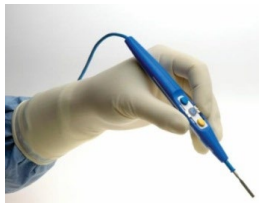
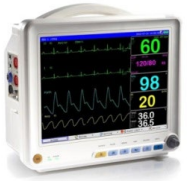
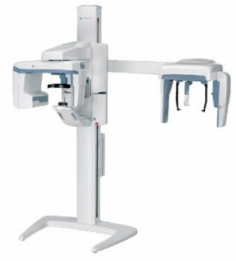
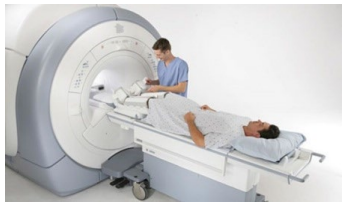
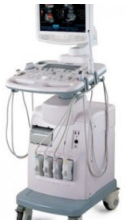
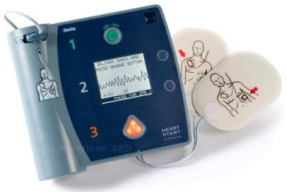
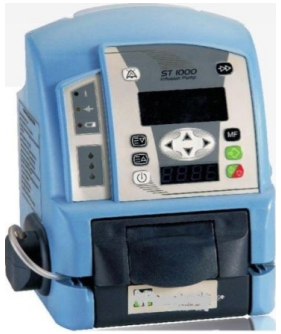
EQUIPMENT TECHNOLOGY MANAGEMENT - GQUIP

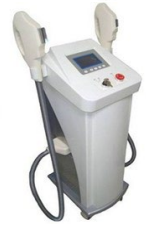











LEGAL MARK

✓ Law No. 6,360/1976 (art. 12)

No product of interest to health, whether national or imported, may be industrialized, offered for sale or delivered for consumption in the Brazilian market before it has been registered in the Ministry of Health.

✓ Law No. 9,782/1999

Creation of the Brazilian Health Regulatory Agency (Anvisa).

✓ Decree No. 8,077/2013

It regulates the conditions for the operation of companies subject to sanitary licensing, and the registration, control and monitoring, within the scope of sanitary surveillance, of the products referred to in Law No. 6,360 of 1976.

KEY REGULATIONS

✓ RDC Anvisa No. 751/2022

It defines the requirements for the Medical Device Registration (Materials and Equipment) (Risk Classes III and IV).

It defines the requirements for Medical Device Notification (Risk Classes I and II).

✓ RDC Anvisa No. 36/2015 (Under review)

It defines the rules for Notification and Registration of *In Vitro* Diagnostic Products (Classes I to IV).

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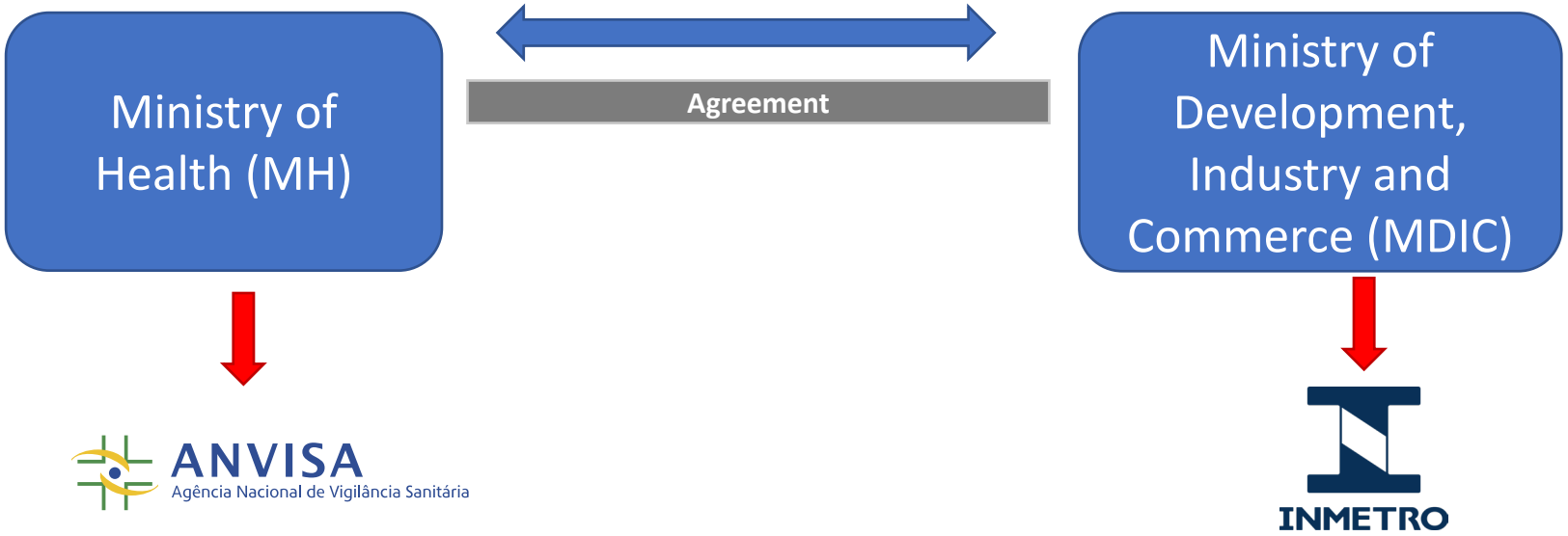
LEGAL MARKS OF MEDICAL DEVICE CONFORMITY ASSESSMENT

- MH Ordinance No. 2043/94 - It establishes the Medical Device Quality Assurance System - “Proequipo/MH” context
- MH/MDIC Ordinance No. 692/2009, which defines the Safety and Quality Assurance of Medical Devices submitted to the sanitary control regime, under the context of “Health Industrial Complex” (it replaces MH Ordinance No. 2043/94);



MEDICAL DEVICE CONFORMITY ASSESSMENT

Brazilian Conformity Assessment System (SBAC)

Agreements with:
ILAC - International Laboratory Accreditation Co-Operation
EA – European Cooperation for Accreditation
IAAC – Interamerican Accreditation Cooperation.

KEY REGULATIONS FOR MEDICAL DEVICE CONFORMITY ASSESSMENT

HEALTH MATERIALS TECHNOLOGY MANAGEMENT - GEMAT

✓ RDC Anvisa No. 539/2021

- It establishes minimum identity and quality requirements for single-use transfusion, gravity infusion, and infusion sets for use with infusion pumps

INMETRO ORDINANCE NO. 461, NOVEMBER 18, 2021 - It approves the Conformity Assessment Requirements for Single-Use Transfusion, Gravity Infusion and Infusion Sets for Use with Infusion Pumps - Consolidated

✓ RDC Anvisa No. 540/2021

- It establishes minimum identity and quality requirements for hypodermic needles and gingival needles.

INMETRO ORDINANCE NO. 84, FEBRUARY 10, 2021 - It approves the Conformity Assessment Requirements for Single-Use Sterile Hypodermic Needles and Sterile Gingival Needles - Consolidated.

✓ RDC Anvisa No. 541/2021

- It establishes minimum identity and quality requirements for single-use sterile hypodermic syringes.

INMETRO ORDINANCE NO. 458, NOVEMBER 17, 2021 - It approves the Conformity Assessment Requirements for Single-Use Sterile Hypodermic Syringes - Consolidated.

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KEY REGULATIONS FOR MEDICAL DEVICE CONFORMITY ASSESSMENT

✓ RDC Anvisa No. 547/2021

- It establishes minimum identity and quality requirements for surgical gloves and gloves for non-surgical procedures made of natural rubber, synthetic rubber, a mix of natural and synthetic rubbers, and polyvinyl chloride rubber, under the health surveillance regime.

INMETRO ORDINANCE NO. 485, DECEMBER 8, 2021 - It approves the Conformity Assessment Requirements for Surgical and Non-Surgical Procedure Gloves, made of natural rubber, and a mix of natural and synthetic rubbers, under the health surveillance regime - Consolidated.

✓ RDC Anvisa No. 550/2021

- It establishes the minimum identity and quality requirements for breast implants and the demand of product conformity certification within the scope of the Brazilian Conformity Assessment System (SBAC).

INMETRO ORDINANCE NO. 5, JANUARY 11, 2022 - It approves the Conformity Assessment Requirements for Breast Implants - Consolidated.

✓ RDC Anvisa No. 554/2021

- It establishes the minimum requirements to be met by Natural Rubber Latex Male Condoms

INMETRO ORDINANCE NO. 266, JUNE 22, 2021 - It approves the Conformity Assessment Requirements for Male Condoms - Consolidated.

KEY REGULATIONS FOR MEDICAL DEVICE CONFORMITY ASSESSMENT

EQUIPMENT TECHNOLOGY MANAGEMENT - GQUIP

RCD Anvisa No. 549/2021 - It provides for procedures for compulsory equipment certification under health surveillance regime

IN No. 116/2021 - It approves the update of the Technical Standards list for equipment conformity certification under health surveillance regime

INMETRO Ordinance No. 384/2020 - It approves the Conformity Assessment Requirements for Equipment under health surveillance regime - Consolidated.

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Example of some Technical Standards listed at IN No. 116/2021

- ABNT NBR IEC 60601-1:2010 + Amendment 1:2016
- ABNT NBR IEC 60601-1-2:2017
- ABNT NBR IEC 60601-1-8:2010 + Amendment 1:2014
- ABNT NBR IEC 60601-2-4:2014
- ABNT NBR IEC 60601-2-25:2014
- ABNT NBR IEC 60601-2-50:2010 + Amendment 1:2019
- ABNT NBR IEC 60601-2-66:2017
- ISO 14457:2012
- ABNT NBR ISO 7176-1:2018

77 Technical Standards

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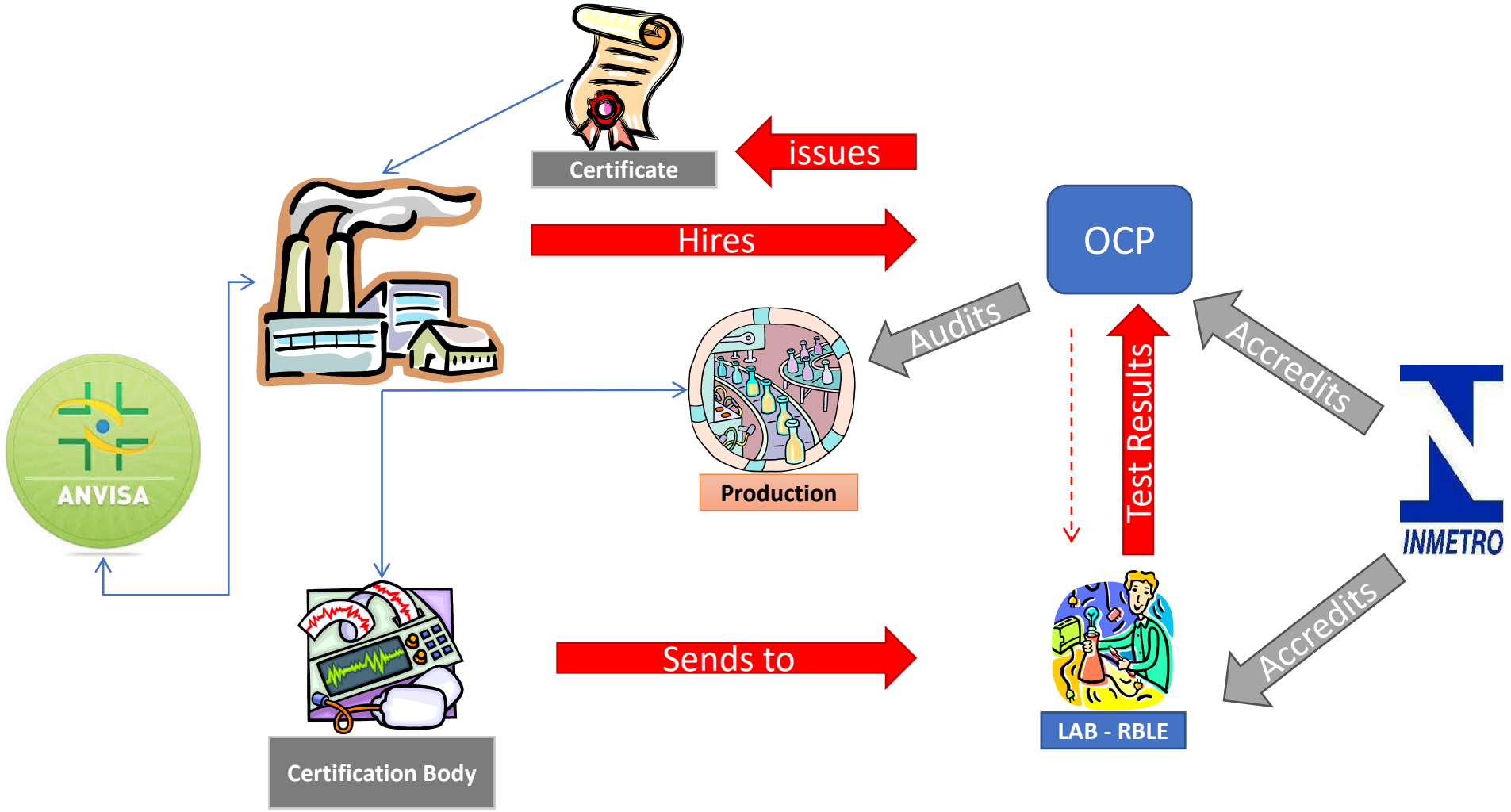
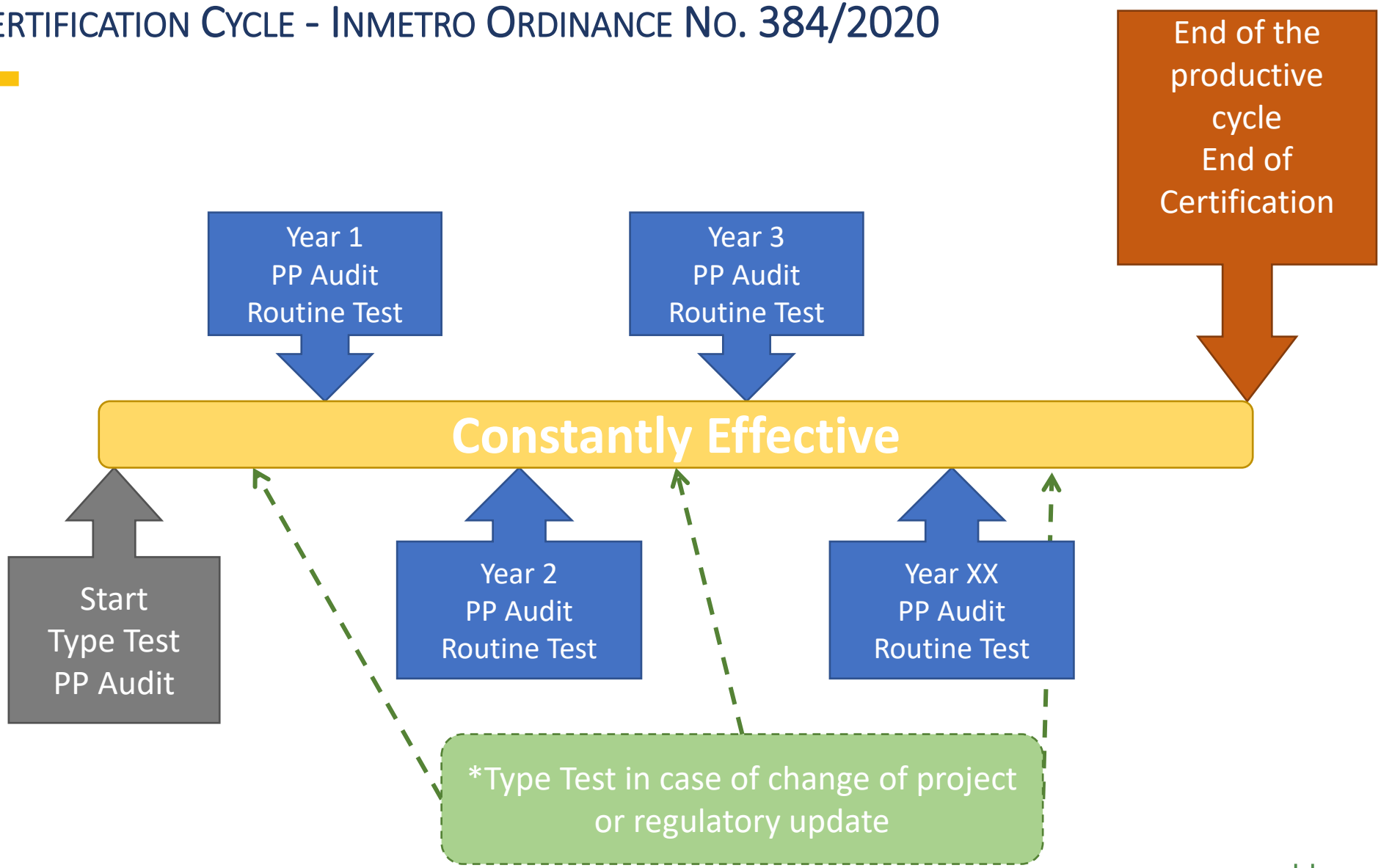
Certification Process



Certification Cycle - Inmetro Ordinance No. 384/2020



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THANK YOU!

Medical Devices Office

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