UL Solutions

WHITE PAPER

Medical Devices for Brazil

Overview of INMETRO Certification Scheme per Ordinance no. 384:2020

LET'S GO

Executive summary

All medical devices sold in Brazil must register with the Agência Nacional de Vigilância Sanitária (ANVISA). ANVISA performs all registration and inspection functions within the agency.

The Regulation “Resolução da Diretoria Colegiada RDC no. 549:2021” by ANVISA provides policy and establishes the INMETRO mandatory certification scheme for electromedical equipment as a pre-requirement to register the product with ANVISA for entry into the local market.

The regulation also indicates the mechanism of “Instrução Normativa” that prescribes the standards and implementation date which each equipment must comply with.

In this document, we cover in detail the requirements per Ordinance no. 384:2020 to achieve and maintain INMETRO Certification under UL Solutions.

Scope of the mandatory INMETRO Certification?
Per Regulation RDC no. 549:2021, the electromedical equipment under INMETRO mandatory certification, including its parts and accessories are:

- Equipment for medical, dental, laboratory or physical therapy, used directly or indirectly for diagnosis, treatment, rehabilitation and monitoring in humans
- Equipment for beautification and aesthetic purposes

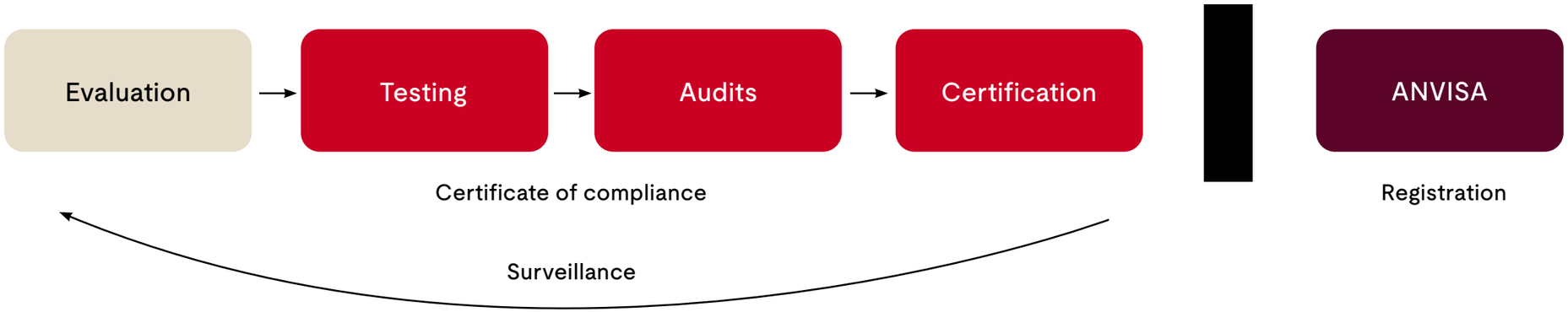
The INMETRO Ordinance 384:2020 covers the INMETRO mandatory certification requirements. All equipment, even including those certified according to previous Ordinances such as 350:2010 and/or 54:2016, must be transitioned and comply with INMETRO Ordinance no. 384:2020.

And the recent “Instrução Normativa” IN no. 283:2024 by ANVISA dated March, 7, 2024 with effective date for April, 1, 2024, prescribes the standards and implementation due date which above equipment must comply with.

Process for new certifications

The certification process consists of four major steps, as indicated below.

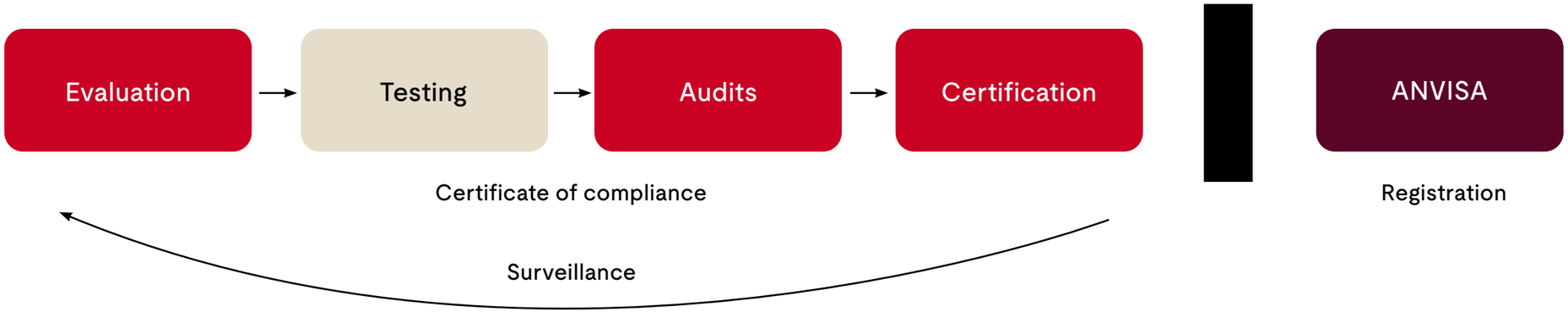
Evaluation: required list



- General product information – Specifications, datasheets, drawings, labeling, list of critical components
- Picture of the product and package with the INMETRO Conformity Label – The Certificate Holder must provide a draft picture or layout showing where the UL-BR and INMETRO Conformity Label would be put on both the product and package. Note that labels should be placed on the product and package before entering the country.
- Risk Management File – This file must be based on ISO 14971. All risk management reference documentation also needs to be included.
- User's manual in Portuguese – The user's manual must be in the local language (Brazilian Portuguese).

Process for new certifications

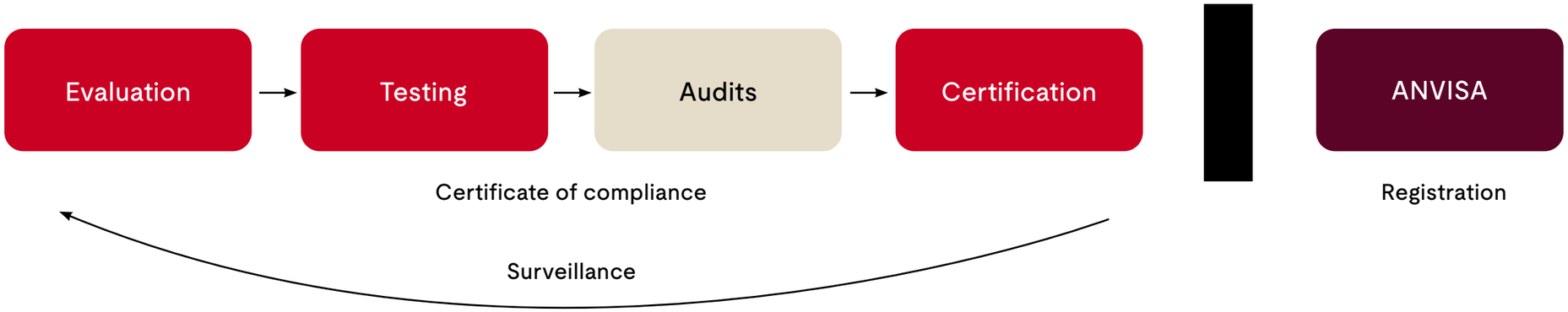
Testing



- Test Reports – must meet two basic requirements
  - They must be issued by any laboratory accredited by any ILAC member for the standard mentioned in the report.
  - They must cover the applicable Brazil standards. Brazil recognizes IEC standards that are translated into Portuguese and then renamed using the prefix “ABNT NBR.”
  - For example: “IEC 60601-1:2005/AMD1:2012/AMD2:2020” is equivalent to “ABNT NBR IEC 60601-1:2010/Emenda 1:2016/Emenda2:2022.”
- ILAC accreditation of the laboratory – Certificate Holder need to provide the accreditation of the laboratory that issued the test reports and the period when the test reports were issued.
- Conformity Test Declaration – A declaration stating that the product remains the same from the issue date of the test reports is required documentation.

Process for new certifications

Audits



Initial audit at the manufacturing location

The scope of the audit is described in both INMETRO Ordinances 384:2020 and 200:2021 and consists of the following activities also described in the following table and sections:

- ISO 13485:2016 clauses
- Assessment of design, risk management, usability, software
- Witness the assembly of the product
- Execution of routine or production line tests
- Use of INMETRO conformity label.

All manufacturing sites where the clauses described in INMETRO Ordinance 384:2020 are implemented will need to be audited.

This means that we need to audit the legal manufacturer and, eventually, the subcontracted manufacturer.

Audits

A. ISO 13485:2016 clauses

Table 1: ABNT NBR ISO 13485:2016 clauses

Requirement	Clause
Quality management system	4
General requirements	4.1
Control of documents	4.2.4
Control of records	4.2.5
Planning of product realization	7.1
Determination of requirements related to the product	7.2.1
Review of requirements related to the product	7.2.2
Customer communication	7.2.3
Customer feedback, including customer complaints	7.2.3.c
Design and development	7.3
Design and development planning	7.3.2
Design and development inputs	7.3.3
Design and development outputs	7.3.4
Design and development review	7.3.5

Requirement	Clause
Design and development verification	7.3.6
Design and development validation	7.3.7
Control of design and development changes	7.3.9
Verification of purchased product	7.4.3
Control of production and service provision	7.5.1
Validation of processes for production and service provision	7.5.6
Identification	7.5.8
Traceability	7.5.9
Preservation of product	7.5.11
Control of monitoring and measuring devices	7.6
Monitoring and measurement of processes	8.2.5
Monitoring and measurement of product	8.2.6
Control of nonconforming product	8.3
Corrective action	8.5.2

Audits

B. Assessment of design, risk management, usability, software
The auditor will check if the documentation provided in the early stages of the process are in compliance with the requirements described in Annex A of the INMETRO Ordinance 384:2020.

C. Witness of the product assembling
The UL Solutions auditor must witness the product assembly. If the family of products consists of more than one version, then the most complete version should be chosen to assemble under witness. This is applicable even if the product hasn't been regularly produced. In this case, the factory should schedule the assembling of some units (to be agreed prior to the audit), so this can be verified in the audit.

D. Witness of routine tests
The routine tests are separate from the full type tests that are generally done on the prototype. They consist of four tests performed by the manufacturers at their facilities and must be conducted on 100% of the units that bear the INMETRO Label and should comply with clauses 8.6, 8.7 and 8.8 of the standard IEC 60601-1. The UL Solutions auditor must witness the execution of the routine tests on the representative sample of the product family.

i. Earthing (clause 8.6)
ii. Leakage current (clause 8.7)
iii. Dielectric strength (clause 8.8, non-destructive)
iv. Functional tests that are defined by the manufacturer and agreed with UL Solutions

Audits

Initial audit at the Certificate Holder
This audit must be performed at the Certificate's Holder facilities in Brazil responsible for the clauses in Table 2.

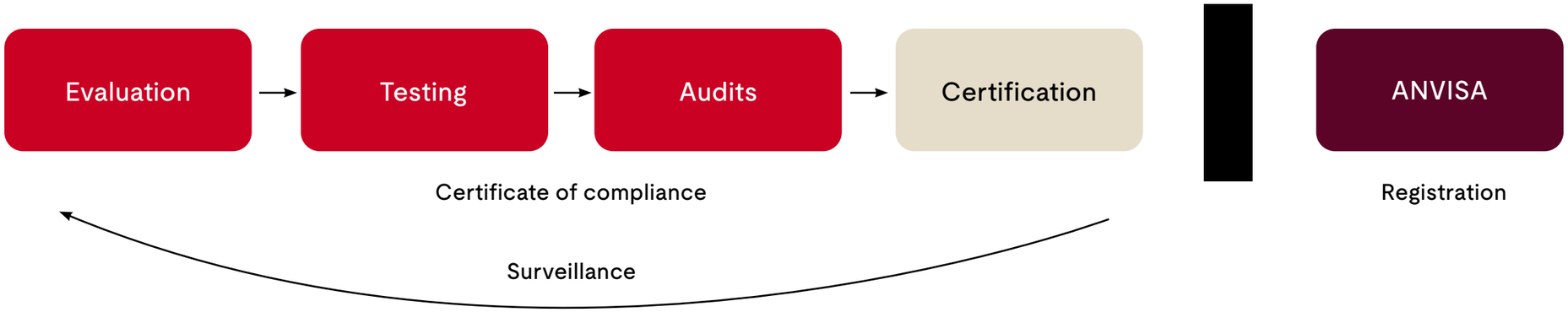
Table 2: ABNT NBR ISO 13485:2016 clauses

Requirement	Clause
Control of documents	4.2.4
Control of records	4.2.5
Customer communication	7.2.3
Identification	7.5.8
Traceability	7.5.9
Verification of purchased product (if applicable)	7.4.3
Preservation of product	7.5.11
Control of monitoring and measuring devices	7.6
Feedback	8.2.1
Control of nonconforming product (if applicable)	8.3
Corrective action	8.5.2

Post-sales services: requirement from ANVISA collegiate board resolution – RDC No.665 dated March 30, 2022 and CLAUSE B.2 OF THE ORDINANCE 384:2020.

Process for new certifications

Certification



The INMETRO conformity certificate is issued upon completion of previous phases and in compliance with regulations in place.

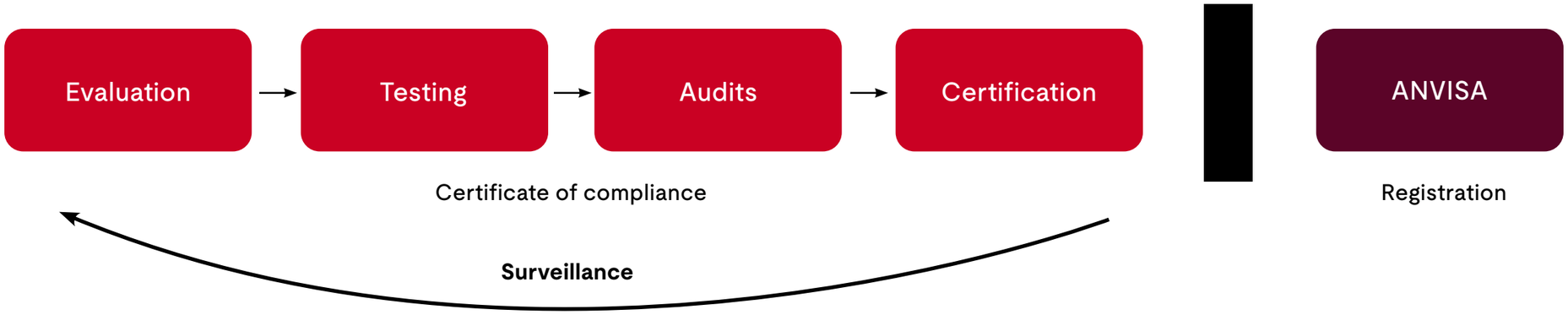
The certificate is sent out to the local Certificate Holder. In parallel, the certificate is uploaded to INMETRO database and displayed on their webpage.

The INMETRO conformity Certificate will not expire once surveillance activities are carried out. The surveillance of the certification is linked to the update of the DHF, execution of maintenance audits and complementary tests if there is a design change that critically affects the safety of the already certified Equipment and, consequently, that require complementary tests.

The surveillance of the certification is subject to compliance with the standards, in accordance with the Anvisa Regulatory Instruction.

Process for new certifications

Surveillance



The surveillance consists of audits on manufacturers and on the Certificate Holder on an annual basis.

The scope of audit is the same as for the initial certification.

At the end of the surveillance audits, UL Solutions must issue a Surveillance Confirmation communication to show that the products comply with all INMETRO Ordinance 384:2020 requirements.

This is required by INMETRO Ordinance 384:2020 and has to be issued to the local Certificate Holder right after all annual surveillance activities have been completed.

It is important to note that the current legislation determines that the interval between surveillance cannot exceed 15 months.

Submission of new products

New products must go through the same procedure described above even if they are manufactured at the same locations UL Solutions regularly audits.

This means that UL Solutions could audit both the manufacturing site(s) and the Certificate Holder.

Use of the INMETRO Conformity Label

The Brazilian Conformity label consists of the INMETRO label and the label of the Brazilian accredited certification body that issues the certificate. The graphics below show the Brazilian conformity that is granted by UL Solutions as part of an INMETRO project.

There are three versions of the label that can be used depending on the available room on the product:

1. The rectangular label shown here must be used if the product has enough room to accommodate it. Any of the three available colors may be used. The minimum size is 50 mm in length.

2. The 20 mm smaller label can be used in case there is not enough room to use the rectangular label above. This logo is only available in black and white.

3. The 11 mm label below can be used if there is not enough room for the 20 mm label.

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