



UL INMETRO CERTIFICATION PROCESS

BASED ON ORDINANCE 54 PUBLISHED BY INMETRO ON
FEB 1ST, 2016 (IN EFFECT SINCE MAY 1ST, 2017)





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.

Brazil's Ordinance 54, Conformity Assessment Requirements for Equipment under Sanitary Surveillance took effect on 01-MAY-2017. Most of its requirements are the same as those of the previous Ordinance 350, but others, such as the scope of factory audits, have been substantially changed. In this document, we discuss in detail the requirements under Ordinance 54 to achieve and maintain INMETRO Certification under UL.

Scope of the mandatory INMETRO Certification?

The scope of INMETRO covers all products listed on both of these documents issued by ANVISA: “Resolução da Diretoria Colegiada RDC-27:2011” (RDC 27) and “INSTRUÇÃO NORMATIVA” (IN). The IN document is periodically updated and includes electro-medical devices and other devices that are not electrically powered, such as dental hand-pieces. This document also defines the implementation date for the compulsory certification for each type of product as well as the standards to be used.

For example, according to the latest IN (IN-22 published in 2017), compliance to the standard IEC 60601-1-12:2014 will be required from 01-DEC-2018.

PROCESS FOR NEW CERTIFICATIONS

- A. Documentation Analysis
- B. Audits at both manufacturing sites and local applicant in Brazil
- C. Issue the certificate (**valid for five years**)



ANALYSIS OF DOCUMENTATION: REQUIRED LIST

A. Test Reports - Must meet two basic requirements

1. They must be issued by any laboratory accredited by any ILAC member for the standard mentioned on the report.
2. They can't be issued more than two years (or four years for specific equipment) from the date the UL INMETRO certification contract (or quotation) is approved.

Non-Conformities: If the report describes non-conformances, the applicant will need to be provided with the proper clarifications as evidence they have been addressed.

Standards: Test reports must reference 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" is equivalent to "ABNT NBR IEC 60601-1:2010 Emenda 1:2016".

- B. ILAC accreditation of the laboratory: Applicants need to provide the accreditation of the laboratory that issued the test reports, and the period when the test reports were issued.
- C. Conformity Test Declaration: A declaration stating that the product remains the same from the issue date of the test reports is required documentation. For example: "We hereby declare that the product(s) XXXX have not gone through any substantial change that would require new laboratory tests, and therefore the provided test reports are still valid."
- D. Risk Management File: This file must be based on ISO 14971:2007 and can be prepared by the applicant. All risk management reference documentation also needs to be included.
- E. INMETRO certificate of the power supply cord: If the product has a power supply cord, it must be INMETRO certified according to standards ABNT NBR NM 60884-1: 2004 and NBR 14136: 2002. The power supply supplier will need to provide the certificate. Certified suppliers can be found on the INMETRO website where all certified manufacturers are listed.
- F. User's manual in Portuguese: The user's manual must be in the local language (Brazilian Portuguese).
- G. Picture of the product and package with the INMETRO mark: The applicant must provide a draft picture or layout showing where the UL+INMETRO mark would be put on both the product and package. Note that marks should be placed on the product and package before entering the country.



AUDITS

Initial audit at the manufacturing location

The scope of the audit is described on both Ordinances 54 and 118¹ and consists of the following activities also described in the following table and sections:

1. ISO 13485 clauses
2. Execution of routine tests
3. Verification of project documentation
4. Witness the assembly of the product

ALL manufacturing sites where the clauses described on the Ordinance 54 are implemented will need to be audited. This means that we need to audit the “Legal Manufacturer,” and eventually the “Subcontracted Manufacturer.”

TABLE 1: ABNT NBR ISO 13485:2004 CLAUSES

Requirement	Clause
Quality management system	4
General requirements	4.1
Control of documents	4.2.3
Control of records	4.2.4
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	7.3.1
Design and development inputs	7.3.2
Design and development outputs	7.3.3
Design and development review	7.3.4
Design and development verification	7.3.5
Design and development validation	7.3.6
Control of design and development changes	7.3.7
Verification of purchased product	7.4.3
Control of production and service provision	7.5.1
Validation of processes for production and service provision	7.5.2
Identification and traceability	7.5.3
Preservation of product	7.5.5
Control of monitoring and measuring devices	7.6
Monitoring and measurement of processes	8.2.3
Monitoring and measurement of product	8.2.4
Control of nonconforming product	8.3
Corrective action	8.5.2

¹ Ordinance 118 is a general certification rule, applicable to a variety of products, including medical devices.

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 mark and should comply with clauses 8.6, 8.7 and 8.8 of the standard IEC 60601-1:2005/AMD1:2012/COR1:2014. The UL auditor must witness the execution of the routine tests on the representative sample of the product family.

- a. Earthing (clause 8.6);
- b. Leakage current (clause 8.7);
- c. Dielectric strength (clause 8.8, non-destructive);
- d. Functional tests that are defined by the manufacturer and agreed with UL.

Project Documentation

The auditor will check if the documentation provided in the early stages of the process (please, see above) are in compliance with the requirements described on tables from 2 to 7 of the Ordinance 54 (Annex A).

Witness of the Product Assembling

The UL 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.

Scope of the Initial Audit at the Brazilian Applicant

This audit has to be performed at the applicant's facilities in Brazil responsible for the clauses in Table 2. UL might have to audit more than one site if the clauses below are implemented in different locations. This is particularly relevant for clauses 7.4.3, 7.5.5 and 7.6, since this could involve auditing a 3rd party warehouse. In other words, if the applicant maintains products in stock, these 3 clauses have to be verified at the warehouse. On the other hand, this is not needed when the product is directly shipped to the final customer.

TABLE 2: SPECIFIC CLAUSES FOR INITIAL INMETRO AUDIT

CLAUSES OF THE ABNT NBR ISO 13485:2004	
Requirement	Clause
Control of documents	4.2.3
Control of records	4.2.4
Customer communication	7.2.3
Identification and traceability	7.5.3
Verification of purchased product (if applicable)	7.4.3
Preservation of product	7.5.5
Control of monitoring and measuring devices	7.6
Monitoring and measurement of processes	8.2.3
Control of nonconforming product (if applicable)	8.3
Corrective action	8.5.2
Post-sales services: REQUIREMENT FROM ANVISA COLLEGIATE BOARD RESOLUTION - RDC No.16 OF MARCH 28, 2013 and CLAUSE B-2 OF THE ORDINANCE 54.	

ANNUAL SURVEILLANCE PROCESS

The annual surveillance is the same as the initial certification audit. The basic difference is that the scope of this audit will have to include all products that are INMETRO certified and manufactured at the same location. If there is more than one INMETRO certified location, each will need to be audited. The annual surveillance takes slightly longer than the initial audit, because one model representing each product family at each site will need to have their routine tests and assembly witnessed by the auditor, even if it is rarely produced.

In addition, UL must issue a “Surveillance Confirmation” communication to confirm that the products still comply with all INMETRO requirements. This is required by the Ordinance 54 and has to be issued to the local applicant right after all annual surveillance activities have been completed.

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

Re-certification

After the 5-year period, the certificate can be renewed for another five years. The procedure for recertification is the same as for new processes. It is important to pay attention to the expiration date of the INMETRO certificate to make sure all documentation is ready for resubmission, including a new set of test reports.

Submission of new products

New products must go through the same procedure described above even if they are manufactured at the same locations UL regularly audits. This means that UL needs to audit both the manufacturing site(s) and the local applicant. However, it’s possible to reduce the scope of the audit if the product is part of a family that is already INMETRO certified.

Conversion from old certificates (350)

Current certificates issued according to the old Ordinance 350 remain valid and will be maintained using this same legislation until the certificate expiration date. However, they will have to be converted into the Ordinance 54 if the product goes through relevant changes that require tests. Also, please note that if the same manufacturing location produces devices according to both legislations (350 and 54), the maintenance process will be done differently and accordance to the respective legislation that was used to certify the product.

Certification of new products that are not in regular production yet

In this particular case, the only change is the fact that the UL auditor won’t find a product that is serially produced, thus the witnessing of its assembly has to be previously arranged with the manufacturer. At least one sample has to be assembled and routine tested during the audit.

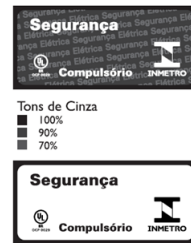


USE OF THE INMETRO MARK

The Brazilian Conformity Mark consists of the INMETRO mark and the mark of the Brazilian accredited certification body that issues the certificate. The graphics below show the Brazilian conformity mark that is granted by UL as part of an INMETRO project. The mark should be put on both product and package before entering Brazil.

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

- a. The rectangular mark 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 50mm in length.



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



- c. The 11 mm mark below can be used if there is not enough room for the 20 mm mark (final art not ready as the UL br logo is missing).





FAQs

Can my test reports be used for INMETRO?

Existing test reports can be used as long as they are issued by ILAC accredited members and are less than two years old. This means that if the test report was issued on Feb 16th, 2017, the contract (or quotation) for product certification has to be signed by Feb 16th, 2019.

The initial pages of the test report contain very useful information such as issue date, version of the standards, location of the laboratory and the accreditation company, that will determine if it can be used in Brazil.

How do I know if certain laboratory is ILAC accredited?

Generally, laboratories are accredited by local entities that are part of ILAC. Canadian laboratories are generally accredited by SCC. Likewise, Italian laboratories are generally accredited by ACCREDIA, which is the Italian accreditation board. However, they are not always accredited by their national entities. It is possible to have a Japanese laboratory accredited by a North American ILAC member.

How do I know if an entity is an ILAC member?

To find out if an entity is an ILAC member, go to www.ilac.org and select the country to show the signatories that are under the ILAC Mutual Recognition Arrangement.

For example: *Is UL Northbrook accredited by ILAC for IEC 60601-2-10? Yes, it is because this location is accredited by IAS that is an ILAC member. Generally, the accreditation scope is public and available on the internet. Click the following link: <https://www.iasonline.org/wp-content/uploads/2017/05/TL-157-Scope.pdf>*

It is important to highlight that the address on the ILAC certificate must match the address mentioned on the test report. In this example, the address on the report should be 333 Pfingsten Road, Northbrook, IL, 60062.

Figure 1: Example of UL Test Report Cover Page

IEC 60601-1 Medical electrical equipment	
Part 1: General requirements for basic safety and essential performance	
Report Reference No.....	
Date of issue.....	16 February 2017
Total number of pages.....	144
CB Testing Laboratory.....	
Address.....	
Applicant's name.....	
Address.....	
Test specification:	
Standard.....	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012
Test procedure.....	CB Scheme
Non-standard test method.....	N/A
Test Report Form No.....	IEC80601_1J
Test Report Form Originator.....	UL(US)
Master TRF.....	2014-07
<small>Copyright © 2014 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved. This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context. If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed. This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.</small>	
Test item description.....	
Trade Mark.....	
Manufacturer.....	Same as applicant
Model/Type reference.....	
Ratings.....	110-120Vac, 50/60 Hz, 2A or 220-240Vac, 50/60 Hz, 1A



INTERNATIONAL ACCREDITATION SERVICE®



SCOPE OF ACCREDITATION

IAS Accreditation Number	TL-157
Company Name	UL LLC
Address: 333 Pfingsten Road, Northbrook, Illinois 60062	

What if the tests are performed at the manufacturer's facilities?

Different testing programs can be used by the manufacturer. These programs are designed by the laboratories and consist of different levels of supervision.

The test programs known as **TMP** (or **WMT**) (Testing at Manufacturer's Premises) and **WTDP** (UL's Witness Test Data Program) are acceptable for INMETRO processes, as long as the tests are witnessed in person AND if the responsible laboratory that is going to issue the report is ILAC accredited.

What should I watch out for in audits performed at the manufacturing facilities?

Routine tests: This is a deviation from other countries. Contact UL in case you have any questions regarding these tests.

Multiple facilities to be audited: UL needs to audit all clauses described in this document even if they are spread across different locations. This has significant impact in costs and logistics, so please let us know in advance if that is the case.

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