Brazil's New INMETRO Ordinance

Understand the requirements, impacts and changes of the newly revised 384:2020 INMETRO ordinance for medical equipment.

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The impact and changes of the revised 384:2020 INMETRO ordinance

Are you currently marketing, or planning to market medical equipment in Brazil? If so, be aware of a new ordinance for compliance assessment requirements for equipment under Health Surveillance Regimen that was published by INMETRO on Dec. 18, 2020. These requirements apply to equipment, including their parts and accessories, for medical, dental, laboratory or physiotherapeutic purposes (directly or indirectly for diagnosis), treatment, rehabilitation, monitoring, and equipment used for embellishment and aesthetics.

Significant changes in the new ordinance, including some that should be good news to manufacturers.

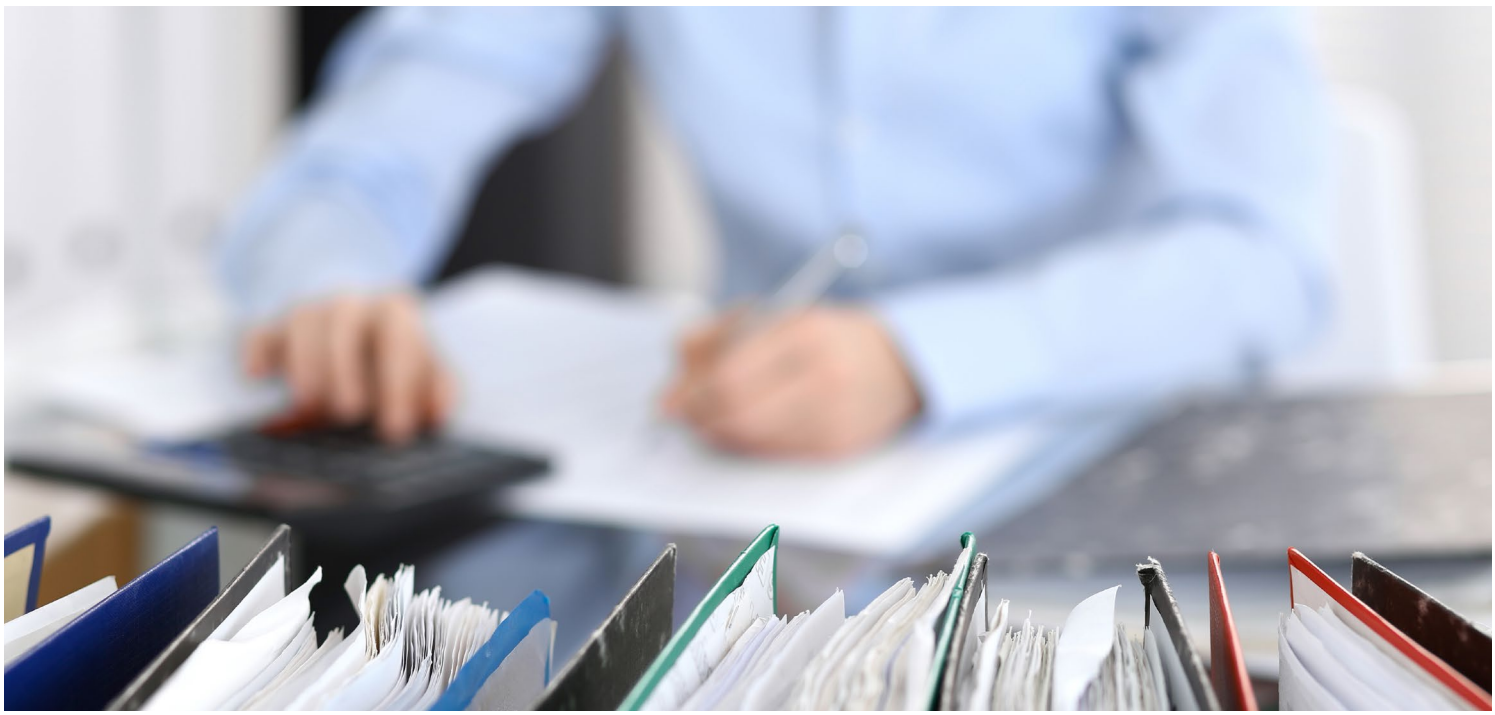
INMETRO audits

The new ordinance could result in reduced audit time. Under INMETRO Ordinance 384:2020, the INMETRO QMS (quality management system) audit may be replaced by several options. In some cases, the INMETRO audit duration may be reduced to audit only the production line, device history record (DHR), device master record (DMR) and routine tests. In cases where the manufacturer is not currently producing a product, the audit can be conducted based on a review of procedures and records.

Additionally, a new INMETRO certificate can be issued without performing an audit if the new product utilizes the same (or similar) production line as another product already under the Certification Body's surveillance program. The documentation analysis must then be performed and documented.

Test Report Age Requirement

The new ordinance removes the test report age (valid date) requirement for test report acceptance, however, the test report(s) must still represent the product's current construction. The original test report, corrections, revisions or amendments will be evaluated along with all changes made to the device. If the Certification Body identifies critical changes that were not evaluated and could impact the product's basic safety or essential performance, additional testing may be required. The standard(s) (including edition) referenced in the test report(s) must be listed in the current ANVISA Normative Instruction (IN49).



Valid (Expiration) Date of INMETRO Certificates

The INMETRO certificate will no longer have a valid (expiration) date. The valid date will appear on the certificate as undetermined and will be aligned with the execution of the surveillance audit and updated where applicable. The applicant is responsible for keeping the INMETRO certificate up to date considering all changes made to the device.

INMETRO Label

The INMETRO label may be affixed on the device and/or packaging in either the country of origin or after entry in Brazil. In cases where the product is small (when the area available for the application of the INMETRO label is not sufficient for the use of the smallest seal size indicated in Annex C), or in the case of sterile single-use equipment, the application of the seal can be done on the packaging.

Timing

For existing certificates issued under INMETRO Ordinance no. 54, of 2016, the Certification Bodies shall update the certification process and certificates to add the reference to the new Ordinance 384:2020 during the next annual surveillance assessment as long as it takes place after June 28, 2021. An important observation to note is that the surveillance process is subject to compliance with the standards defined in the current ANVISA Normative Instruction (IN49).

INMETRO testing and certification

UL offers mandatory product certification and factory inspections required by the regulations, including the software evaluations as required by INMETRO. These evaluations include:

- Testing at or by an ILAC accredited laboratory to applicable IEC 60601 based Brazilian Association of Technical Standards (ABNT) NBR standards
- Quality system audit based on ISO 13485
- Product production/assembly of each representative product family witnessed on site by an INMETRO auditor

For more information on Brazil's new INMETRO ordinance, go to www.ul.com/news/brazils-new-inmetro-ordinance.

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