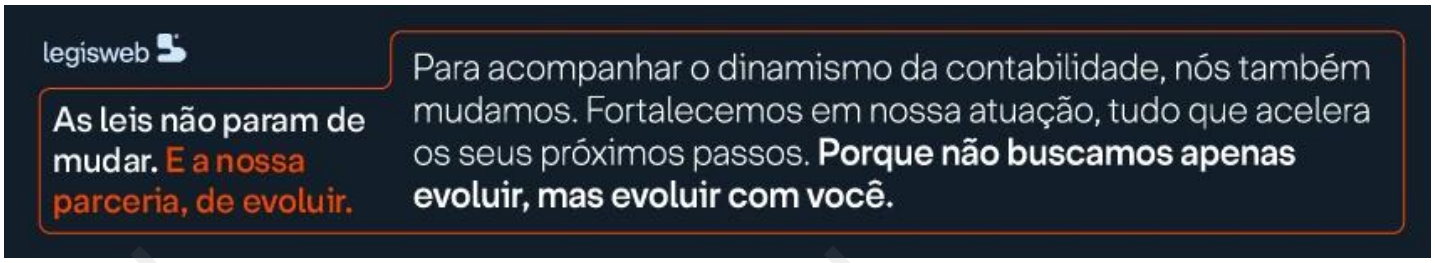
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INMETRO ORDINANCE NO. 384 OF 12/18/2020

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Approves the Conformity Assessment Requirements for Equipment under the Sanitary Surveillance Regime - Consolidated.



THE PRESIDENT OF THE NATIONAL INSTITUTE OF METROLOGY, QUALITY AND TECHNOLOGY - INMETRO, in the exercise of the competence granted to him by articles 4, paragraph 2, of Law No. 5,966, of December 11, 1973, and 3, items I and IV, of Law No. 9,933, of December 20, 1999, combined with the provisions of articles 18, item V, of Annex I to Decree No. 6,275, of November 28, 2007, and 105, item V, of the Annex to Ordinance No. 2, of January 4, 2017, of the then Ministry of Industry, Foreign Trade and Services, considering what is determined by Decree No. 10,139, of November 28, 2019, and what is contained in SEI Process No. 0052600.006080/2019-60, Resolves:

Object and Scope of Application

Art. 1 - The Conformity Assessment Requirements and the Specifications for the Conformity Identification Seal for Equipment under the Sanitary Surveillance Regime - Consolidated are hereby approved, established, respectively, in Annexes I and II available in http://www.inmetro.gov.br/legislacao.

Paragraph 1 - The conformity assessment, by means of the certification mechanism, must be carried out by a Product Certification Body - OCP, established in Brazil and accredited by Inmetro, according to the Requirements approved herein.

Paragraph 2 - These Requirements apply to equipment, including its parts and accessories, for medical, dental, laboratory or physiotherapeutic purposes, used directly or indirectly for diagnosis, treatment, rehabilitation and monitoring in human beings, and to equipment for beautification and aesthetics purposes.

Paragraph 3 - Equipment that does not fall under Anvisa RDC No. 27, of 2011 or substitutive, are excluded from the scope of coverage of these Requirements.

Paragraph 4 - The National Health Surveillance Agency - Anvisa is responsible for defining, by means of a Normative Instruction - IN or Collegiate Board Resolution - RDC, as to the requirement - compulsory nature - of the certification of Equipment under the Sanitary Surveillance Regime.

Art. 2 - It is not within the sphere of legal competence of Inmetro to regulate the technical regulation of equipment under the sanitary surveillance regime, as well as the exercise of administrative police power regarding the object, and it is exclusively responsible for supervising the use of the trademark, focusing on compliance with the rules of Conformity Assessment.

Deadlines and Transitional Provisions

Article 3 - Within a maximum period of 6 months, as of the effective date of this Ordinance, new certificates may only be issued based on the Requirements hereby approved.

Art. 4 - For certificates already issued based on Inmetro Ordinance No. 54, published in the Federal Official Gazette of June 2, 2016, section 1, pages 70 to 71, the Product Certification Bodies must adapt the certification processes and review the certificates, to include the reference to the Ordinance hereby approved, in the maintenance following the publication of this Ordinance, provided that this does not occur in a period of less than 6 (six) months, when they may still comply with Ordinance No. 54, of 2016.

Article 5 - For the purpose of feeding the Certified Products and Services Bank - ProdCert, the Product Certification Bodies must fill in the mandatory field "validity of the certificate" with a period of 5 (five) years, counted from the date of issue, with revalidation every 5 (five) years, in order to maintain the "active" status of the certificate. until the system is modified, at which point the validity will become "indeterminate".

Article 6 - The maintenance of certifications or recertifications that were initiated until April 30, 2017 may also be carried out based on Ordinance 350, published in the Federal Official Gazette of September 9, 2010, section 1, page 67, up to the limit of the validity of five (5) years of the certificates issued until April 30, 2018.

Sole Paragraph - The validity of the certificates issued in accordance with the caput may expire early if the Product Certification Body (OCP) or Anvisa identifies that the manufacturer has modified the project, critically affecting the safety of the equipment. In this case, the original certificate is cancelled and the manufacturer is required to adapt the equipment to the requirements of the ordinance now approved for a new certification.

Article 7 - A transition period is established for the dismemberment of certificates issued for identical products, manufactured in different locations (plants), into individual certificates as established by Inmetro Ordinance No. 118, published in the Federal Official Gazette of March 9, 2015, section 1, pages 76 to 77 and the Ordinance hereby approved, which ends in 50 (fifty) months, counted from the effective date of this Ordinance.

Art. 8 - The OCP must inform Inmetro and Anvisa of the occurrences according to sub-items 6.3.3.5 and 6.3.4.1 of the RAC approved by this Ordinance, as well as the design modifications that are identified in audits and have not been informed by the manufacturer to the OCP as established herein, which critically affect the safety of the Equipment under Sanitary Surveillance already certified.

Paragraph 1 - Communications to Anvisa must be made through the electronic address certifica.eletromedicos@anvisa.gov.br.

Paragraph 2 - Communications to Inmetro for equipment under metrological control must be made through the electronic addresses dicol@inmetro.gov.br.

Paragraph 3 - Communications to Inmetro for equipment without metrological control must be made through the address divet@inmetro.gov.br.

Revocation clause

Article 9 - The following Inmetro Ordinances are hereby revoked:

I - No. 350, of September 6, 2010, published in the Federal Official Gazette of September 9, 2010, section 01, page 67, on April 30, 2023;

II - No. 54, of February 1, 2016, published in the Federal Official Gazette of February 2, 2016, section 01, pages 70 to 71, within six (6) months from the effective date of this Ordinance; and

III - No. 544, of November 24, 2016, published in the Federal Official Gazette of November 29, 2016, section 01, page 41, within six (6) months from the effective date of this Ordinance.

Art. 10 - This Ordinance enters into force on December 28, 2020, according to art. 4 of Decree No. 10,139/2019.

MARCOS HELENO GUERSON DE OLIVEIRA JUNIOR