



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: Brazil If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: National Institute of Metrology, Quality and Technology-INMETRO Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: National Institute of Metrology, Quality and Technology-INMETRO Telephone: +(55) 21 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Website: http://www.inmetro.gov.br/barreirastecnicas
3. Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [X], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): equipment under a health surveillance.
5. Title, number of pages and language(s) of the notified document: Ordinance Nº. 407, 26 August 2014 - Conformity Assessment procedures for equipment under a health surveillance. (74 pages in Portuguese)
6. Description of content: Establish criteria for Conformity Assessment procedures for equipment under a health surveillance, attending the requirements of the related standards in Complementary Documents, for the safety of users. These requirements apply to equipment, including parts and accessories, with medical, dental, laboratory and physiotherapy purpose, directly or indirectly used for diagnosis, treatment, rehabilitation and monitoring in humans; and equipment with the purpose of beautification and aesthetics.
7. Objective and rationale, including the nature of urgent problems where applicable: Consumer protection; Safety.
8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União) Nº 165, 28 August 2014, section 1, page 94; (2) Resolução do Conselho Nacional de Metrologia, Normalização e Qualidade Industrial - CONMETRO Nº 04, de 02 de dezembro de 2002; Portaria Interministerial MS/MDIC nº 692, de 08 de abril de 2009; Portaria Interministerial MS/MDIC nº 16, de 17 de dezembro de 2010; Portaria Ministerial MS/MDIC nº 206, de 21 de junho de 2013; Portaria Inmetro nº 350, de 06 de setembro de 2010; (3) Brazilian Official Journal; (4) IEC 60601; ISSO/IEC 80601; ABNT NBR IEC

60601; ABNT NBR ISO/IEC 80601.

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| 9. Proposed date of adoption:
Proposed date of entry into force: | } Upon publication in the Official Journal after subsequent discussions on consolidating the final text with the representatives of the sector and, received comments have been taken into account. |
| 10. Final date for comments: 28 September 2014 | |
| 11. Text available from: National enquiry point [], or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:
http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC002160.pdf | |