



4 December 2018

(18-7667)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>BRAZIL</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Website: www.inmetro.gov.br/barreirastecnicas 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: Brazilian Health Regulatory Agency (Anvisa) http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=33294
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 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): Medical equipment (ICS 11.040), Aids for deaf and hearing impaired people (ICS 11.180.15), Aids for incontinence and ostomy (ICS 11.180.20).
5. Title, number of pages and language(s) of the notified document: Normative Instruction 29, 27 November 2018 (Instrução Normativa 29, de 27 de Novembro de 2018) published in section 1, page 133 of the Brazilian Official Gazette number 228, 28 November 2018. (1 page(s), in Portuguese)
6. Description of content: This Normative Instruction provides the update of Annex I of Normative Instruction 4/2015 (Instrução Normativa 4, de 24 de Setembro de 2015) approving the list of technical standards to be adopted in the conformity assessment, and the updating of Annex II of IN 4/2015 (List of dates regarding the entrance into force of the standards to be adopted in the compulsory third party certification), within the scope of the Brazilian System of Conformity Assessment (SBAC). This Normative Instruction enter into force on the date of its publication.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: <ul style="list-style-type: none">• Normative Instruction 4, 24 September 2015.• ABNT NBR IEC 60601-1-2:2010;

	<ul style="list-style-type: none">• ABNT NBR IEC 60601-1-2:2017• IEC 60601
9.	Proposed date of adoption: On the date of its publication Proposed date of entry into force: On the date of its publication
10.	Final date for comments: Not applicable
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: Agency Responsible Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília - DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/documents/10181/3682321/IN_29_2018_.pdf/5e93116b-56c5-4665-99be-6bd29602e413