



Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Notifying Member: BRAZIL If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: Brazilian Health Regulatory Agency (Anvisa) Name and address (including telephone and fax numbers, e-mail and web-site 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 Web-site: www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall be sent to http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=28231
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 devices
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution nº 257, 28 September 2016 (Resolução RDC nº 257, de 28 de setembro de 2016). 12 pages, Portuguese.
6. Description of content: Draft Technical Resolution nº 257, 28 September 2016 (Resolução RDC nº 257, de 28 de setembro de 2016), regarding the requirements for registration of medical devices and also their reuse prohibition, labelling and use instructions. The manufacturers and importers of medical devices which hold valid registration in Brazil has the period of 1 (one) year to request to ANVISA, from the date of publication of this Resolution, changes needed to adequacy for labelling and use instructions, mentioned on articles 10 to 14 of this Resolution. This Resolution revokes the Resolution RDC 156/2006 and the Specific Resolution RE 2.605/2006.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8. Relevant documents: 1) Brazilian Official Journal (Diário Oficial da União), September 28, 2016, Section 1, p. 697; 2) Not stated; 3) Brazilian Official Journal; 4) Not stated.
9. Proposed date of adoption: on the date of publication. Proposed date of entry into force: On the date of publication.
10. Final date for comments: December 5, 2016
11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the 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/10181/3032238/%281%29Proposta+de+norma+em+discuss%C3%A3o.pdf/4dbaf0f8-591b-419e-9675-1db3992f584e