



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: ANVISA –Brazilian Health Regulatory Agency 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 2563.2821 Telefax: +(55) 21 2502.6542 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=10343
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 (HS: 90.00)
5. Title, number of pages and language(s) of the notified document: Draft Resolution nº 11, April 10 th 2013 (Consulta Pública nº 11, de 10 de abril de 2013) – Draft Technical Regulation that establishes requirements to enable certifying bodies and to use testing laboratories to perform activities of interest to Anvisa in the area of medical devices. (9 pages, Portuguese)
6. Description of content: This draft Technical Regulation has the objective to establish requirements to enable Certifying Bodies and to use testing laboratories to perform activities of interest to Anvisa in the area of medical devices.
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), April 10 th 2013; (2) Not Applicable (3) Brazilian Official Journal (4) Not Applicable; When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.

9. Proposed date of adoption: to be determined after the end of the consultation period.

Proposed date of entry into force: 365 days after its adoption

10. Final date for comments: 16 June, 2013.

11. Texts available from: National enquiry point [] 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

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