



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 2563.2821 Telefax: +(55) 21 2502.6542 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall also be sent to http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=10976
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, In Vitro Diagnostics. HS: 90.18
5. Title, number of pages and language(s) of the notified document: Draft Resolution nº 08, March 28 2013 – Anvisa Normative Instruction establishing which requirements of the Technical Regulation of Good Manufacturing Practices for Medical Devices and In Vitro Diagnostics are applicable to companies that perform activities of import, distribution and storage. (3 pages, Portuguese)
6. Description of content: This draft Technical Regulation establishes the scope of application of the provisions of the Technical Regulation of Good Manufacturing Practices for Medical Devices and In Vitro Diagnostics for companies that perform activities of import, distribution and storage.
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 1 st

2013; Section 1 Draft Resolution (Consulta Pública) number 08, March 28 th , 2013, issued by Brazilian Health Regulatory Agency – Anvisa; (2) Not Applicable; (3) Brazilian Official Journal; (4) Not Applicable	
9.	Proposed date of adoption: Proposed date of entry into force: } to be determined after the end of the consultation period.
10.	Final date for comments: June 6 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 SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: 55 61 3462-5402 E-mail: rel@anvisa.gov.br Website: www.anvisa.gov.br http://portal.anvisa.gov.br/wps/wcm/connect/619564004f1b47fba26fbec88f4b6a31/Consulta+P%C3%BAblica+n%C2%B0+8-retificada-02.04.2013+GGIMP.pdf?MOD=AJPERES