WORLD TRADE ORGANIZATION

Committee on Technical Barriers to Trade N/A

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:** ANVISA - Brazilian Health Regulatory Agency **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 2563.2821 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=13493
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):** Health Products
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 50, November 12th 2013 ☐ Draft Resolution (RDC) which establishes requirements to prove compliance with Good Manufacturing Practices (GMP) for registration of medical devices in Brazil. (3 pages, in Portuguese)
6.	**Description of content:** This draft Technical Regulation establishes requirements to prove compliance with Good Manufacturing Practices (GMP) for registration of medical devices at Anvisa. This Draft Resolution will revoke Anvisa Resolution RDC 25/2009 and Normative Instruction 2/2011.

7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety
8.	**Relevant documents:** (1) Brazilian Official Journal (Diário Oficial da União) n 222, November 14st 2013, Section ,1page 53; (2) Draft Resolution (Consulta Pública) number 50, November 12th, 2013, issued by Brazilian Health Regulatory Agency ☐ Anvisa; (3) Brazilian Official Journal; (4) Not Applicable
9.	**Proposed date of adoption:** } To be determined after the end of the consultation period. **Proposed date of entry into force:** To be determined after the end of the consultation period.
10.	**Final date for comments:** 21 December 2013
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:** 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 Websit http://portal.anvisa.gov.br/wps/wcm/connect/054e708041d3793fa9c3ed9d63c1a945/Consulta+P%C3%BAblica+n%C2%B0+50+DIREG.pdf?MOD=AJPERES