WORLD TRADE ORGANIZATION

G/TBT/N/BRA/591

03 June 2014

(14-3228)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

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 Surveillance 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) 2563.2840 Telefax: +55 (21) 2563.5637 Email: barreirastecnicas@inmetro.gov.br Website: www.inmetro.gov.br/barreirastecnicas
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 Resolution nº 24, May 13th 2014, that defines the requirements for registration at Anvisa of low and medium risk medical devices for sanitary control. (10 pages, in Portuguese)
6.	**Description of content:** This draft Resolution establishes the requirements for registration at Anvisa of low and medium risk medical devices for sanitary control. This draft Resolution applies to medical devices classified as Class Risk I and II. According to this draft technical regulation, to request the registration of medical devices classified as Class Risk I and II and its alteration, the manufacturer or the importer must present a list of specific documents. The technical dossier, containing all documents and information, must be regularly updated by the national manufacturer or the importer to Anvisa. According to this draft technical regulation, the medical devices Class Risk I and II registered at Anvisa are exempt from revalidation. They must observe GMP, technical standards and specific standards, according the Brazilian System of Conformity Assessment – SBAC, when applicable, as expressed in Article 10 of the draft technical regulation.
7.	**Objective and rationale, including the nature of urgent problems where applicable:**

	Protection of human health or safety
8.	**Relevant documents:** Brazilian Official Journal (Diário Oficial da União), May 20th 2014; Section 1, p. 36, Draft Resolution (Consulta Pública) number 24, May 13th 2014, issued by Brazilian Health Surveillance Agency – Anvisa. 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:** } 30 days after the date of adoption.
10.	**Final date for comments:** 25 July 2014
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 Surveillance 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 http://portal.anvisa.gov.br/wps/wcm/connect/8df5d3804411512f846dbe94043333b2/Consulta+P%C3%BAblica+n%C2%B0+24+GGTPS.pdf?MOD=AJPERES