WORLD TRADE ORGANIZATION

G/TBT/N/BRA/590

03 June 2014

(14-3227)

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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):** In vitro diagnosis products
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 23, May 13th 2014, that disposes about in vitro diagnosis products. (19 pages, in Portuguese)
6.	**Description of content:** This draft Resolution establishes the necessary requirements to register, cancel, alter and revalidate in vitro diagnosis products. This draft resolution applies to products which are manufactured or imported to Brazil and which are classified according to some risk criteria and its goals. According to this draft technical regulation, the registration, alteration, revalidation and cancellation of the registration of these products are made under de presentation of some general and documental requirements. For purposes of regularization of the products at Anvisa, IVD products are classified under the following classes: I - Class I: low-risk products to individuals and low risk to public health; II - Class II: products of medium risk to individuals and / or low risk to public health;

	III - Class III: high-risk products to individuals and / or medium risk to public health; and IV - Class IV: high-risk products to individuals and high risk to public health. According to the risk classification of the IVD product, it will have different requirements to be regularized at Anvisa, as expressed in articles 18, 19 and 20 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 23, 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:** } Upon publication in the Official Journal after received comments have been taken into account **Proposed date of entry into force:** } Upon publication in the Official Journal after received comments have been taken into account
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 Web http://portal.anvisa.gov.br/wps/wcm/connect/da2b6180441149408452be94043333b2/consulta+p%C3%BAblica+n%C2%B0+23+GGTPS.pdf?MOD=AJPERES