

WORLD TRADE ORGANIZATION

G/TBT/N/BRA

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Member to Agreement notifying: <u>BRAZIL</u> 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, Standardization and Industrial Quality-INMETRO Telephone: +(55) 21 2563.2821 Telefax: +(55) 21 2502.6542 Email: barreirastecnicas@inmetro.gov.br Web-site: 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): Products for <i>in vitro</i> diagnosis.
5. Title, number of pages and language(s) of the notified document: Draft Resolution n° 40, June 25 th 2012 – Establishes criteria for grouping of <i>in vitro</i> diagnosis products into families for registration and cadastre purposes. (3 pages, Portuguese)
6. Description of content: This Resolution approves criteria for grouping of <i>in vitro</i> diagnosis products into families for registration and cadastre purposes. Products registered in accordance with Board Resolution – RDC n. 97, November 9 th , 2000, must comply with this Resolution when requesting revalidation. Name or composition changes are forbidden before the adequacy of cadastre and registration to the provisions of this Resolution. Resolution RDC n° 97, November 9 th 2000, no longer applies to <i>in vitro</i> diagnosis products.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health.

8.	Relevant documents: Brazilian Official Journal (Diário Oficial da União), June 27 th 2012; Section 1. Draft Resolution (Consulta Pública) number 40, June 25 th 2012, issued by the Brazilian Health Regulatory Agency – Anvisa; When adopted, it will be published at 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: to be determined after the end of the consultation period.
10.	Final date for comments: July 27 th , 2012.
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: National enquiry point 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/01325a804bc538b1a6dcffbc0f9d5b29/Consulta+P%C3%BAblica+N%C2%B0+40+GGTPS_nova.pdf?MOD=AJPERES