

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): Health products
5. Title, number of pages and language(s) of the notified document: Draft Resolution nº 48, July 13 th 2012 – Establishes the protocol for electronic issuance of Product Certificate and Certificate to Foreign Government (5 pages, Portuguese)
6. Description of content: This draft technical Resolution establishes the protocol for electronic issuance of Product Certificate and Certificate to Foreign Government relating to health products. The documents issued before the validity of the Resolution are valid until the expiration date of the registration of the product.
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), July 23 rd 2012; (2) Not Applicable; (3) 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: August 22nd, 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/c0f29b004c14b6f79167d1dc39d59d3e/Consulta+P%C3%BAblica+n%C2%B0+48+GGTPS.pdf?MOD=AJPERES>