



Committee on Technical Barriers to Trade

NOTIFICATION

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

1. Notifying Member: BRAZIL If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: Anvisa – Brazilian Health Surveillance Agency 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, Quality and Technology - INMETRO Telephone: +(55) 21 2563.2840 Telefax: +(55) 21 2563.5637 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=21031
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): register of <i>in vitro</i> diagnosis products used on HIV self-testing.
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution nº 52, June 10 th 2015, regarding the register of <i>in vitro</i> diagnosis products used on HIV self-testing (3 pages, Portuguese).
6. Description of content: Draft Technical Resolution nº 52, June 10 th 2015, regarding the register of <i>in vitro</i> diagnosis products used on HIV self-testing. This Draft Technical Resolution proposes the definition of criteria to registering of <i>in vitro</i> diagnosis products used on HIV self-testing.
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), June 11 th 2015; Section 1, p. 29; 2) Not stated; 3) Brazilian Official Journal; 4) Not Stated.
9. Proposed date of adoption: To be determined after the end of the consultation period. Proposed date of entry into force: On the date of the publication.

10. Final date for comments: August 17th, 2015.

11. Texts 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

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