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 2563.2820** **Telefax: +(55) 21 2502.6542** 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=17388
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):** labelling of medical devices containing natural rubber latex
5.	**Title, number of pages and language(s) of the notified document:** Draft Technical Resolution nº 70, September 9th 2014, regarding the standardization of phrases stating the presence of natural rubber latex on medical device labels (3 pages, Portuguese).
6.	**Description of content:** Draft Technical Resolution nº 70, September 9th 2014, regarding the standardization of phrases stating the presence of natural rubber latex on medical device labels. This draft Technical Resolution applies to the medical devices defined as medical products and *in vitro* diagnostic products. According to this draft resolution, the labelling of medical devices which composition contains natural rubber latex must include the following featured warnings: "THIS PRODUCT CONTAINS NATURAL RUBBER LATEX. ITS USE MAY CAUSE ALLERGIC REACTIONS IN PEOPLE SENSITIVE TO LATEX". In case of small packaging, the warning can alternatively be: "CONTAINS NATURAL LATEX. IT MAY CAUSE ALLERGY". The labelling of the products must be corrected in 180 days from the date of publication of this resolution. The products which were manufactured before the entry into force of this regulation and during the adequacy period can be marketed until the expiration date.

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), September 10th 2014; Section 1, p. 70, Draft Resolution (Consulta Pública) number 70, September 9th 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:** } to be determined after the end of the consultation period.
10.	**Final date for comments:** November 17th, 2014.
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 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 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/wps/wcm/connect/dec52380456c04aaa0efa40bb3a02a58/Consulta+P%C3%BAblica+n%C2%B0+70+GGTPS.pdf?MOD=AJPERES