**Committee on Technical Barriers to Trade**

Original: English

## NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Brazil<br>**If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** ANVISA – Brazilian Health Surveillance Agency<br>**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<br><br>Telephone: +(55) 21 2563.2821<br>Telefax: +(55) 21 2502.6542<br>Email: barreirastecnicas@inmetro.gov.br<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):** Clinical trials with medical devices. |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Resolution nº 64, August 1st 2014, that disposes about the clinical trials with medical devices accomplished in Brazil. (24 pages, in Portuguese) |
| **6.** | **Description of content:**<br><br>This draft technical resolution establishes the procedures and requirements to the accomplishment of clinical trials with medical devices in Brazil, including the procedures and requirements to the approval by the Brazilian Health Surveillance Agency – ANVISA of the Dossier of a Medical Device Clinical Investigation. The accomplishment of clinical trials involving medical devices in Brazil requires prior consent of ANVISA.<br><br>This draft resolution is applicable to clinical investigation with medical devices of risk classes III and IV, which will have all its clinical development, or part of it, in Brazil, in order to generate evidences of its efficacy, performance or safety, necessary to the registration by ANVISA.<br><br>The clinical investigations with medical devices that have been initiated before the entry into force of this technical resolution, and that are not yet regularized at ANVISA, will have one year to adjust themselves to this regulation. The non-compliance with the terms of this regulation will be considered sanitary infraction, according to Federal Law 6.437/77. |

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| | This draft resolution revokes the following technical Resolutions: RDC n. 39/2008; RDC n. 36/2012; and items 1 and 1.1 of Section I, items 2, 2.1 and 2.1.1 of Section II of Chapter XXVI of RDC 81/2008, for clinical trials with medical devices. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:**<br>Protection of human health or safety |
| **8.** | **Relevant documents:** Brazilian Official Journal (Diário Oficial da União), August 04th 2014; Section 1, p. 73, Draft Resolution (Consulta Pública) number 64, August 01th 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.<br>**Proposed date of entry into force:** To be determined after the end of the consultation period. |
| **10.** | **Final date for comments:** 11 September 2014 |
| **11.** | **Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Brazilian Health Surveillance Agency – ANVISA<br>SIA, Trecho 5, Área Especial 57<br>Brasília – DF / Brazil<br>CEP: 71.205-050<br>Phone.: 55 61 3462-5402<br>E-mail: rel@anvisa.gov.br<br>Website: www.anvisa.gov.br<br>http://portal.anvisa.gov.br/wps/wcm/connect/e467158044fb026bbc7ebcc5b6e3ae4b/Consulta+P%C3%BAblica+n%C2%B0+64+SUALI.pdf?MOD=AJPERES |