



Committee on Technical Barriers to Trade

NOTIFICATION

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

<b>1. Notifying Member:</b> BRAZIL <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Brazilian Health Regulatory Agency (Anvisa) <b>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:</b>  National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2765 Telefax: +(55) 21 2563.5637 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a>  <b>The comments to this Draft Regulation shall be sent to</b> <a href="http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=33366">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=33366</a>
<b>3. Notified under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Medical Devices
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Technical Resolution n. 371, 1 <sup>st</sup> August 2017. 3 pages, Portuguese.
<b>6. Description of content:</b> This Draft Resolution provides for the expiration date of the registration of medical devices. The term of 10 years for the validity of the registration of medical devices is established. This Resolution applies to medical devices within the scope of "correlatos" referenced by Law No. 6,360, dated September 23, 1976. Medical devices include medical products and diagnostic products for in vitro use, as defined in Ministerial Order MS / MDIC No. 692, of April 8, 2009.  The validity periods of registrations granted prior to the publication of this Resolution are automatically extended to 10 years, counted from the last publication of registration or revalidation.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human Health
<b>8. Relevant documents :</b> (1) Brazilian Official Journal (Diário Oficial da União) Nº 147, 02 August 2017, section 1, page 32; (2) Law 9.782, 26 January 1999 (Lei nº 9.782, de 26 de janeiro de 1999); (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 its publication.

**10. Final date for comments:** 6<sup>th</sup> October, 2017

**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:**

Agency Responsible  
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