



**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=33294">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=33294</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> HS Chapter 90
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Resolution 528, 17 May 2018. 11 pages, Portuguese.
<b>6. Description of content:</b> This Resolution has the objective of defining the requirements of the Notification regime for sanitary control of low-risk medical devices exempted from registration pursuant to § 1 of article 25 of Law 6,360, 23 September, 1976.  This Resolution applies to low-risk medical devices classified in risk class I, according to the classification rules available in RDC 185, 22 October, 2001, and RDC 36, 26 August, 2015.
<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), 22 May 2018; (2) Law 6.360, 23 September 1976; Resolutions: RDC 185, 22 October 2001; RDC 36, 26 August 2015; RDC 185, 22 October 2001, and RDC 36, 26 August 2015; (3) Brazilian Official Journal (Diário Oficial da União);(4) Not stated.
<b>9. Proposed date of adoption:</b> On the date of its publication <b>Proposed date of entry into force:</b> 60 days after its publication

**10. Final date for comments:**

**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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<http://portal.anvisa.gov.br/documents/10181/3741322/CONSULTA+P%C3%9ABLICA+N%C2%BA+528+GGTPS.pdf/5d3a219b-22cc-4e7b-bd27-e2ac367d7c08>