WORLD TRADE ORGANIZATION

G/TBT/N/BRA/815

31 May 2018

(18-3262)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (Anvisa) **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) Telephone: +(55) 21 2563.2765 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=33294
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):** HS Chapter 90
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution 528, 17 May 2018. (11 page(s), in Portuguese)
6.	**Description of content:** 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.
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), 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.
9.	**Proposed date of adoption:** On the date of its publication **Proposed date of entry into force:** 60 days after its publication

10.	**Final date for comments:** Not applicable
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Agency Responsible Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF/Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/documents/10181/3741322/CONSULTA+P%C3%9ABLICA+N%C2%BA+528+GGTPS.pdf/5d3a219b-22cc-4e7b-bd27-e2ac367d7c08