



3 January 2019

(19-0008)

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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: <u>BRAZIL</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2840 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=28757 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: Brazilian Health Regulatory Agency (Anvisa)
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): Medical devices
5. Title, number of pages and language(s) of the notified document: Draft Resolution 584, 21 December 2018, published by Brazilian Official Gazette (5 page(s), in Portuguese)
6. Description of content: This draft resolution proposes the medical devices classification as single use or reusable, among other measures. This resolution has the objective of establishing the medical device classification as single use or reusable for regularization with Anvisa, as well as information to be considered on the instructions for use and the label of such devices. This resolution does not apply to in vitro diagnostic products. This resolution applies to manufacturers and importers of medical devices, registration holders, as well as health services. It also applies to the processing companies of health products regarding planning and execution of processing activities of medical devices. The registry holder is responsible for evaluating and establishing the classification of the device in one of the options presented in this document, from the project of the medical device, based on technical-scientific evidence, risk assessment and validation of project and applicable process.

<p>Manufacturers shall define, establish and document the technical-scientific rationale that corroborates the proposed classification for the medical device.</p> <p>The Resolution of Collegiate Board of Directors - RDC No. 156 of 2006 and Specific Resolution - RE No. 2605, of 2006 is hereby revoked.</p> <p>This Resolution shall enter into force 60 days from the date of its publication.</p>	
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8.	Relevant documents: Not Applicable
9.	Proposed date of adoption: 60 days from the date of its publication. Proposed date of entry into force: 60 days from the date of its publication.
10.	Final date for comments: 60 days from notification
11.	Texts available from: National enquiry point [] 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/10181/3898778/CONSULTA+PUBLICA+N+453+GGMED.pdf/bb63a56f-9d2f-4776-9eee-93c239449e1b http://portal.anvisa.gov.br/documents/10181/3898778/RET_CP_453_2017.pdf/5ee841a3-254c-4380-b8e4-971400046b25