



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: 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 2563.2817 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): In vitro diagnosis products
5. Title, number of pages and language(s) of the notified document: Draft Resolution Nº 540, 10 July 2018 (3 page(s), in Portuguese) Published in the Official Journal Number 134, 13 July 2018; Section 1 page 80
6. Description of content: This Draft Resolution 540/2018 changes Normative Instruction nº 03, 26 August 2015, notified under the document G/TBT/N/BRA/590/Add.1 , establishing the permission to group in vitro diagnosis products into systems. The Draft Resolution Nº 540, 10 July 2018 is available at http://portal.anvisa.gov.br/documents/10181/4379139/Minuta+de+Consulta+P%C3%BAblica.pdf/5543de17-1531-4171-b65f-b19694bac245
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: Normative Instruction nº 03, 26 August 2015, Published in the Official Journal Number 164, 27 August 2015; Section 1, page 49 and notified under the document G/TBT/N/BRA/590/Add.1 (Normative Instruction nº 03 is available at http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=27/08/2015&jornal=1&pagina=49&totalArquivos=96)

9. Proposed date of adoption: On the date of its publication. To be determined after the end of the comments period

Proposed date of entry into force: To be determined after the end of the comments period

10. Final date for comments: 19 August 2018

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
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