Committee on Technical Barriers to Trade

NOTIFICATION

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

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (Anvisa) **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:** 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):**
5.	**Title, number of pages and language(s) of the notified document:** Normative Instruction number 24, 17 May 2018. (1 page, Portuguese).
6.	**Description of content:** This Normative Instruction establishes the parameters of the Technical Norm ISO 15197: 2013 - In vitro diagnostic test systems - Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus, as requirements to be adopted and observed by the manufacturers of self-test instruments for glucose and its consumables for registration purposes, changes and revalidation of registration with Anvisa. The items of the Technical Dossier provided in art. 29 of the Resolution of the Collegiate Board of Directors - RDC 36 of August 26, 2015, applicable to the instruments for glucose self-test and its consumables must be met through the inclusion of reports prepared according to the analytical performance evaluation chapter of the Standard Technique ISO 15197: 2013. The reports prepared, cited in article 2, shall be presented within a maximum period of 180 (one hundred and eighty) days after the publication of this Normative Instruction. Product registrations that do not demonstrate compliance with the requirements of ISO 15197: 2013 will be cancelled. In the event that the Technical Standard indicated in this Normative Instruction be replaced by an updated version, the updated version will be required according to the

	transition period recommended by the text of the updated Technical Standard. Failure to comply with the Technical Note requirements within the established deadline will result in the cancellation of the registration of the product in question.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** Resolution RDC 36, 26 August 2015 notified under the document G/TBT/N/BRA/590/Add.1
9.	**Proposed date of adoption:** On the date of its publication **Proposed date of entry into force:** On the date of 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 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/10181/2718376/IN_24_2018_.pdf/4381cad6-3c9f-4a1d-9ccc-ca07f9234539