



10 April 2026

(26-2793)

Page: 1/2

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 (Articles 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 2145.3817 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
3. Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [X], 5.7.1 [], 3.2 [], 7.2 [], Other:
4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): Health care technology (ICS code(s): 11)
5. Details of notified document(s) (title, number of pages and languages, means of access): Draft Resolution 1391, 27 March 2026.; (2 page(s), in Portuguese) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://members.wto.org/crnattachments/2026/TBT/BRA/26_01988_00_x.pdf https://anvisalegis.datalegis.net/action/UrlPublicasAction.php?acao=abrirAtoPublico&num_ato=00001391&sgl_tipo=CPB&sgl_orgao=ANVISA/MS&vlr_ano=2026&seq_ato=222&cod_modulo=134&cod_menu=1696 Comment form: https://pesquisa.anvisa.gov.br/index.php/914654?lang=pt-BR
6. Description of content: This draft resolution proposes the international alignment of parameters for the validation of analytical methods for medicines by revising RDC 166/2017.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: -
9. Proposed date of adoption: To be determined Proposed date of entry into force: To be determined

10. Provision of comments

Final date for comments: 9 June 2026

[X] 60 days from notification

Contact details of agency or authority designated to handle comments regarding the notification:

International Affairs Office
Brazilian Health Regulatory Agency - Anvisa
+55 (61) 3462-5402/5404/5406
rel@anvisa.gov.br