WORLD TRADE ORGANIZATION

G/TBT/N/BRA/1314

4 April 2022

(22-2690)

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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 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 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ],3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** HS (3003-3004) - Medicaments
5.	**Title, number of pages and language(s) of the notified document:** Normative Instruction number 122, 09 March 2022; (3 page(s), in Portuguese)
6.	**Description of content:** This Normative Instruction contains provisions on inspection procedures in Good Clinical Practice for clinical trials with drugs.
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:** 1 April 2022 **Proposed date of entry into force:** 1 April 2022
10.	**Final date for comments:** Not applied

11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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Website: www.anvisa.gov.br

http://antigo.anvisa.gov.br/documents/10181/6407870/IN_122_2022_.pdf/53a4f3f3-2187-4bcf-b59d-f6145c202b98