WORLD TRADE ORGANIZATION

G/TBT/N/BRA/1506

19 October 2023

(23-7043)

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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):** Medical equipment (ICS code(s): 11.040)
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution 1208, 16 October 2023; (2 page(s), in Portuguese)
6.	**Description of content:** This draft resolution proposes changes to administrative procedures for granting Good Practices Certification Manufacturing and Certification of Good Distribution and/or Storage Practices, to enable the increase in the validity period of certificates of good manufacturing practices (CBPF) of medical device manufacturers granted through the Medical Device Single Audit Program - MDSAP.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The increase in the validity period of CBPFs from medical device manufacturers granted through the MDSAP program aims to reduce the regulatory cost for companies and increase adherence to the MDSAP program, thus reducing Anvisa's certification liability and the number of national and international meetings carried out by the National health surveillance system (SNV), so that Anvisa and SNVS can direct their resources to higher risk actions. Furthermore, increasing the number of companies participating in the program would represent an increase in the number of companies that receive annual monitoring, for which Anvisa receives updated reports from Auditing Bodies, thus reducing the risk associated with the manufacturing of the respective medical devices.; 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.	**Final date for comments:** 8 December 2023
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** 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 The final text is available only in Portuguese and can be downloaded at: Draft: http://antigo.anvisa.gov.br/documents/10181/6668081/consulta+_publica_1208_2023+SGCOL+DP+.pdf/bd6c874d-f7df-480b-8d80-290350ea5b62 Comment form: https://pesquisa.anvisa.gov.br/index.php/872368?lang=pt-BR The link of the comment form is going to be available only on 25 October 2023. https://members.wto.org/crnattachments/2023/TBT/BRA/23_13055_00_x.pdf