



Committee on Technical Barriers to Trade

NOTIFICATION

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

<p><b>1. Notifying Member:</b> BRAZIL <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b></p>
<p><b>2. Agency responsible:</b> Brazilian Health Regulatory Agency (Anvisa) <b>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:</b>  National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2765 Telefax: +(55) 21 2563.5637 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a></p>
<p><b>3. Notified under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b></p>
<p><b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Good Distribution and/or Warehousing Practices</p>
<p><b>5. Title, number of pages and language(s) of the notified document:</b> Resolution - RDC n. 217, February 20<sup>th</sup>, 2018. Portuguese, 1 page - Certification of Good Manufacturing Practices and Certification of Good Distribution and/or Warehousing Practices.</p>
<p><b>6. Description of content:</b> Changes the Resolution - RDC Nº 39, August 14th, 2013, which provides for administrative procedures to grant Certification of Good Manufacturing Practices and Certification of Good Distribution and / or Warehousing Practices.</p> <p>Art. 1º The article 4 of the Resolution - RDC Nº 39, August 14th, 2013, which provides for administrative procedures to grant Certification of Good Manufacturing Practices and Certification of Good Distribution and / or Warehousing Practices, becomes effective with the following wording:</p> <p>“Art. 4 ... Paragraph 1. In order to subsidize the granting of the certification referred to in the caput of this article, Anvisa may use confidential information on inspections received under Agreements or Accords with health authorities of other countries.</p> <p>Paragraph 2. The granting of the certification referred to in the caput of this article may occur upon presentation of a valid audit report issued by a third auditor recognized by Anvisa, according to specific regulations, and applicable to companies located in the national territory, Mercosur and other countries.” (NR)</p> <p>Art. 2. Paragraph 3 of art. 5 of the Resolution - RDC Nº 39, of 2013, shall become</p>

effective with the following wording:

"Art. 5 ...

Paragraph 3. Anvisa may establish exceptions to the provisions of the caput of this article, which aim to favor the efficiency and optimization of resources related to international inspections, according to previously defined criteria." (NR)

Art. 3. This Resolution revokes the Resolution - RDC nº 179, September 27 th, 2017.

Art. 4. This Resolution comes into force on the date of its publication.

**7. Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health

**8. Relevant documents:** G/TBT/N/BRA/749

**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  
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[http://portal.anvisa.gov.br/documents/10181/3612364/RDC\\_217\\_2018\\_.pdf/c510c05b-5693-469e-81b4-36bbd21324e5](http://portal.anvisa.gov.br/documents/10181/3612364/RDC_217_2018_.pdf/c510c05b-5693-469e-81b4-36bbd21324e5)