



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
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): Product registration
5. Title, number of pages and language(s) of the notified document: Resolution - RDC n. 212, January 22 th , 2018. Portuguese, 1 page - procedures related to the revalidation of product registration and provides other measures.
6. Description of content: This Resolution changes the Resolution - RDC No. 250 of October 20, 2004, which provides for procedures related to the revalidation of product registration and provides other measures. The caput of art. 1 and of art. 4 of the Resolution - RDC No. 250, dated October 20, 2004, shall become effective with the following wording: "Article 1. The revalidation of the registration must be requested in advance of a maximum of twelve months and a minimum of six months of the date of maturity of the registration, being considered automatically revalidated, regardless of the decision, if it has not been rendered until the day of termination of that." "Art. 4 In the counting of the term to request the revalidation of the record, the final day of validity will be considered as the day of the beginning to count down the maximum advance of twelve months and minimum of six months of the day of registration, under the terms of the previous article." It is revoked the paragraph 3 of art. 2 of the Resolution - RDC No. 250, 2004.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health

8. Relevant documents: Resolution – RDC nº 250 of October 20 th , 2004.
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/10181/3426501/RDC_212_2018_.pdf/09992788-8fa5-435b-8424-5f2214964ed4