



Para: "emsur@mrecic.gov.ar" <emsur@mrecic.gov.ar>, "repbol@rree.gob.bo" <repbol@rree.gob.bo>, "brasaladi@itamaraty.gov.br" <brasaladi@itamaraty.gov.br>, "chilealadi@direcon.gob.cl" <chilealadi@direcon.gob.cl>, "euruguay@cancilleria.gov.co" <euruguay@cancilleria.gov.co>
cc: Lea Contier <lcontier@Inmetro.gov.br>, Andre Luis de Sousa dos Santos <alsantos@inmetro.gov.br>
cco:
Asunto: Proposed Notification (from Brazil) to the WTO
De: barreirastecnicas <barreirastecnicas@inmetro.gov.br> - Jueves 05/12/2019 04:16 p.m.

1 anexo



form_omc_1628.doc

ALADI - BRASIL

1553 507919

Dear Sirs,

Please find attached a notification from Brazil issued by Brazilian Health Regulatory Agency - ANVISA. The Normative instruction 49 , of 22 November 2019, that establishes the list of technical requirements for conformity-assessment of products subject to public health surveillance under the scope of the Brazilian Conformity Assessment System, as prescribed by the Resolution – RDC 27, of 21 June 2011.

Kind Regards,



Brazilian WTO/TBT Enquiry Point

National Institute of Metrology, Quality and Technology - Inmetro

E-mail: barreirastecnicas@inmetro.gov.br

<http://www.inmetro.gov.br/barreirastecnicas>



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 2563.2840 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): HS Code: products subject to public health surveillance.
5. Title, number of pages and language(s) of the notified document: Normative instruction number 49, November 22 nd , 2019. Number of pages: 12; Language(s): Portuguese.
6. Description of content: This Normative Instruction establishes the list of technical requirements for conformity-assessment of products subject to public health surveillance under the scope of the Brazilian Conformity Assessment System, as prescribed by the Resolution – RDC number 27, June 21 st , 2011.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health.
8. Relevant documents: Resolution - RDC number 27, June 21st, 2011
9. Proposed date of adoption: In the date of its publication. Proposed date of entry into force: In the date of its publication.
10. Final date for comments: Not applied.
11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: Assessoria de Assuntos Internacionais - AINTE International Affairs Office

Agência Nacional de Vigilância Sanitária - Anvisa

Brazilian Health Regulatory Agency

Tel: +(55 61) 3462 5402/5404/5406

E-mail: rel@anvisa.gov.br

http://portal.anvisa.gov.br/documents/10181/3682321/%281%29IN_49_2019_.pdf/2c0a291e-8936-4e55-ad07-6f22fdbe41ab