



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 (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): Environment. Health protection. Safety (ICS code(s): 13)
5. Title, number of pages and language(s) of the notified document: Draft resolution 1249, 02 May 2024; (59 page(s), in Portuguese)
6. Description of content: This Draft Resolution contains provisions on the identification and classification of the degree of risk of economic activities subject to health surveillance.
7. Objective and rationale, including the nature of urgent problems where applicable: It is necessary to harmonize guidelines and procedures to simplify the process of legalization, authorization, licensing and operation of companies or economic activities of interest to health surveillance through a risk classification model.; 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: 11 July 2024

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

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Phone.: +(55) 61 3462.5402

Website: www.anvisa.gov.br

The final text is available only in Portuguese and can be downloaded at:

1 file(s) attached.

Draft:

<https://antigo.anvisa.gov.br/documents/10181/6585013/CONSULTA+P%C3%9ABLICA+N%C2%BA+1249+ASNVS.pdf/01cb8510-2980-4a35-b838-d52360ae24bd> Comment form:

<https://pesquisa.anvisa.gov.br/index.php/393848?lang=pt-BR> The comment form link will be available on 13 May 2024.