



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 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 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): HS Code(s): 30041090, 30049099, 30042019 (artificial tears and lubricating eye drops)
5. Title, number of pages and language(s) of the notified document: Resolution – RDC number 458, 21 December 2020. Language(s): Portuguese. Number of pages(s): 4. Resolution: http://antigo.anvisa.gov.br/documents/10181/6111703/RDC_458_2020_.pdf/e66310da-4d68-4b32-be31-7b117849d74d
6. Description of content: This resolution establishes the technical requirements for the market registration process of artificial tears and lubricating eye drops and changes the Resolution – RDC number 185, October 22 nd , 2001, which regulates the market registration process of medical devices.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: : 1) Brazilian Official Gazette 245 on 23 December 2020, section 1, page 127 2) RDC number 185, 22 October 2001 https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-458-de-21-de-dezembro-de-2020-295779360 http://antigo.anvisa.gov.br/documents/10181/2718376/%282%29RDC_185_2001_COMP.pdf/aa2210c7-a354-469e-b60c-e5824a53c828

9. Proposed date of adoption: 2 January 2021

Proposed date of entry into force: 2 January 2021

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:

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