



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 2563.2918 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): 300210, 30029010 (blood plasma and blood derivatives).
5. Title, number of pages and language(s) of the notified document: Draft resolution number 727, September 25 th , 2019. Number of pages: 17; Language(s): Portuguese. Draft: Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=50589
6. Description of content: This draft resolution establishes the technical requirements of good practice for obtaining, processing, distribution, and use of surplus from blood banks that supply blood plasma as processing material for blood derivatives manufacture.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União) 191, 02 October 2019, section 1, page 802; (2) Not applied; (3) Brazilian Official Journal; (4) Not applied
9. Proposed date of adoption: To be determined after the end of the consultation period. Proposed date of entry into force: To be determined after the end of the consultation period.
10. Final date for comments: December 9th, 2019
11. Texts available from: National enquiry point [X] or address, telephone and fax

numbers and email and website addresses, if available, of other body:

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http://portal.anvisa.gov.br/documents/10181/5648805/SEI_ANVISA+-+0748935+-+Consulta+P%C3%BAblica+N%C2%B0+727.pdf/57c0b964-c4d9-4cfe-be53-967334f35240

<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=02/10/2019&jornal=515&pagina=802>