



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): 30045020 (infusion sets for single use)
5. Title, number of pages and language(s) of the notified document: Draft resolution number 710, September 16 th , 2019. Number of pages: 6; Language(s): Portuguese.
6. Description of content: This draft resolution proposes the revision of the Resolution – RDC number 4, February 4 th , 2011, which establishes the minimum requirements of identity and quality for transfusion, infusion and transfusion pumps sets for single use. Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=50302
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health.
8. Relevant documents: Resolution – RDC number 4, February 4th, 2011
9. Proposed date of adoption: To be determined after the end of the consultation period. Proposed date of entry into force: In the date of its publication.
10. Final date for comments: November 8th, 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: Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050

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<http://portal.anvisa.gov.br/documents/10181/5636067/Consulta+P%C3%ABblica+n%C2%BA+710-2019.pdf/3522d23b-a466-4828-ab49-0e369194538c>