



Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Notifying Member: BRAZIL 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, e-mail and web-site 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 2563.2765 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): Linear or two-dimensional bar code
5. Title, number of pages and language(s) of the notified document: Resolution – RDC nº 232 of 20 June 2018 – Language (s): Portuguese Number of pages: 3 pages
6. Description of content: This Resolution establishes the obligation to include a linear or two-dimensional bar code on stent traceability labels for coronary arteries, pharmacological stents for coronary arteries, and implants for hip and knee arthroplasty. Article 1. It is established the mandatory inclusion of linear barcode or two-dimensional, in accordance with IMDRF / UDI document WG / N7 Final: 2013 - UDI Guidance: Unique Device Identification (UDI) of Medical Devices on traceability labels for single identification of stents for coronary arteries, coronary artery stents, and implants for hip and knee arthroplasty, for traceability and control purposes to be performed within the scope of the National Registry of Implants - RNI. Article 3. The bar code shall contain the following data: I - device identifier; II - date of validity; and III - batch or serial number. Article 4. The provision of the bar code should not prejudice the visualization of the other information provided in the current legislation for traceability labels. Article 6. A bar code other than the one specified in this Resolution may not be included

<p>in the traceability label.</p> <p>Article 7. The availability of traceability labels containing the bar code on medical device packaging shall be made by the manufacturer or importer.</p> <p>Article 8. The inclusion of the bar code in the labels of traceability will not be considered a change for the purposes of registration, dispensing authorization or notification to ANVISA.</p> <p>Single paragraph. Medical devices manufactured prior to the effective date of this Resolution are exempt from the requirements established in this regulation.</p> <p>Article 10. This Resolution comes into force two (2) years after its publication</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health</p>
<p>8. Relevant documents: (1) Brazilian Official Journal 120, 25 June 2018 (Diário Oficial da União de 25 de Junho de 2018); (2) RDC nº 59 of 25 August 2008; (3) Brazilian Official Journal (Diário Oficial da União); (4) Not stated</p>
<p>9. Proposed date of adoption: On the date of its publication</p> <p>Proposed date of entry into force: 2 (two) years after its publication</p>
<p>10. Final date for comments: Not applicable</p>
<p>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</p> <p>Coordinator of International Liaison and Regulatory Convergence International Affairs Office Brazilian Health Regulatory Agency - ANVISA Tel: +55 (61) 3462-5402/5404/5406 E-mail: rel@anvisa.gov.br Website: www.anvisa.gov.br</p> <p>http://portal.anvisa.gov.br/documents/10181/4580265/RDC_232_2018_COMP.pdf/e8380b40-da26-4e8e-84fa-e61c147d8182</p>