



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): medical devices (2936, 2937, 3001, 3002, 3003, 3004, 3006)
5. Title, number of pages and language(s) of the notified document: Normative Instruction number 68, 1 September 2020. Language(s): Portuguese. Number of pages: 2.
6. Description of content: This Normative Instruction establishes the inclusion of a declaration in the label of medical devices informing the existence of a new formula changing its composition.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: 1) Brazilian Official Gazette 170 on 03 September 2020, section 1, page 74 2) Brazilian Official Gazette 170 on 03 September 2020, section 1, page 74 3) Resolution of the Collegiate Board - RDC No. 421 of 01 September 2020 https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-68-de-1-de-setembro-de-2020-275656283 https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-421-de-1-de-setembro-de-2020-275656506 http://antigo.anvisa.gov.br/legislacao#/visualizar/432064
9. Proposed date of adoption: 1 September 2021 Proposed date of entry into force: 1 September 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:

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