



### NOTIFICATION

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

<b>1. Notifying Member:</b> <u>Brazil</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Brazilian Health Regulatory Agency (ANVISA) <b>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:</b>  National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Telefax: +(55) 21 2563.5637 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b>  HS Code(s): medical devices (2936, 2937, 3001, 3002, 3003, 3004, 3006)
<b>5. Title, number of pages and language(s) of the notified document:</b> Resolution – RDC number 423, 16 September 2020. <b>Language(s):</b> Portuguese. <b>Number of pages:</b> 9.  Resolution: <a href="http://antigo.anvisa.gov.br/legislacao#/visualizar/432115">http://antigo.anvisa.gov.br/legislacao#/visualizar/432115</a>
<b>6. Description of content:</b> This Resolution changes the Resolution – RDC number 27, 21 June 2011, the Resolution – RDC number 36, 26 August, 2015, and the Resolution – RDC number 40, 26 August, 2015; and establishes the cancellation of the registration system for medical devices classified as Risk I and II classes, which must be registered in the notification regime.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health.
<b>8. Relevant documents:</b> 1) Brazilian Official Gazette 180 on 18 September 2020, section 1, page 110 2) Term of Opening of Proceedings (TAP) No. 106 of 21/09/2020 3) Motivation about the proposal and justification of exemptions from RIA and Public Consultation  <a href="https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-423-de-16-de-setembro-de-2020-278150627">https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-423-de-16-de-setembro-de-2020-278150627</a>  <a href="http://antigo.anvisa.gov.br/legislacao#/visualizar-etapa/433538">http://antigo.anvisa.gov.br/legislacao#/visualizar-etapa/433538</a>  <a href="http://antigo.anvisa.gov.br/legislacao#/visualizar/432115">http://antigo.anvisa.gov.br/legislacao#/visualizar/432115</a>
<b>9. Proposed date of adoption:</b> In the date of its publication.

<b>Proposed date of entry into force:</b> In the date of its publication.
<b>10. Final date for comments:</b> Not applied.
<b>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b> Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: <a href="http://www.anvisa.gov.br">www.anvisa.gov.br</a>