



### 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 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 403, July 21 <sup>st</sup> , 2020. <b>Language(s):</b> Portuguese. <b>Number of pages:</b> 3.  Resolution: <a href="http://portal.anvisa.gov.br/documents/10181/5963581/RDC_403_2020_.pdf/abffeadb-3528-4899-b24a-66940da6ab8e">http://portal.anvisa.gov.br/documents/10181/5963581/RDC_403_2020_.pdf/abffeadb-3528-4899-b24a-66940da6ab8e</a>
<b>6. Description of content:</b> This resolution changes the Resolution – RDC number 36, August 26 <sup>th</sup> , 2015, and the Resolution – RDC number 40, August 26 <sup>th</sup> , 2015 in order to waive the obligation of certified translation of documents in English or Spanish to submit a request of market authorization for medical devices.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health.
<b>8. Relevant documents:</b> <a href="#">Resolution – RDC number 36, August 26<sup>th</sup>, 2015</a> <a href="#">Resolution – RDC number 40, August 26<sup>th</sup>, 2015</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>

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