



### 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> The Brazilian Health Regulatory Agency <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 2563.2840 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 [ ], 2.10.1 [X], 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): 2936, 2937, 2941,3001, 3002, 3003, 3004, 3005, 3006 (medical devices and pharmaceutical products)
<b>5. Title, number of pages and language(s) of the notified document:</b> Resolution – RDC number 483, 19 March 2021. <b>Language(s):</b> Portuguese. <b>Number of pages:</b> 10.  Resolution: <a href="http://antigo.anvisa.gov.br/documents/10181/6245812/RDC_483_2021_.pdf/b56d6659-d848-4904-a601-301179ed63f0">http://antigo.anvisa.gov.br/documents/10181/6245812/RDC_483_2021_.pdf/b56d6659-d848-4904-a601-301179ed63f0</a>
<b>6. Description of content:</b> This resolution establishes exceptional and temporary technical requirements for the import of new medical devices and medicines identified as indispensable for the use in healthcare services due to the international public health emergency related to the SARS-CoV-2.
<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 53-C on 19 March 2021, section 1, page 1  <a href="https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-483-de-19-de-marco-de-2021-309557207">https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-483-de-19-de-marco-de-2021-309557207</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.

**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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