



### 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>  3003-3004 (HS)
<b>5. Title, number of pages and language(s) of the notified document:</b> Resolution – RDC number 519, 10 June 2021. <b>Language(s):</b> Portuguese. <b>Number of pages:</b> 2.
<b>6. Description of content:</b>  RDC No. 519 amends the Resolution 56, 8 October 2014, which provides for the Certification of Good Practices for conducting Bioavailability/Bioequivalence studies of medicines and other measures.
<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 111 on 16 June 2021, section 1, page 244 2) RDC No. 56, 8 October 2014  <a href="https://www.in.gov.br/web/dou/-/resolucao-rdc-n-519-de-10-de-junho-de-2021-326187667">https://www.in.gov.br/web/dou/-/resolucao-rdc-n-519-de-10-de-junho-de-2021-326187667</a>  <a href="http://antigo.anvisa.gov.br/documents/10181/3676755/RDC_56_2014_COMP.pdf/45796ab0-d665-4c00-8785-b544a680c1ba">http://antigo.anvisa.gov.br/documents/10181/3676755/RDC_56_2014_COMP.pdf/45796ab0-d665-4c00-8785-b544a680c1ba</a>
<b>9. Proposed date of adoption:</b> 16 June 2021 <b>Proposed date of entry into force:</b> 16 June 2021
<b>10. Final date for comments:</b> 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:**

[http://antigo.anvisa.gov.br/documents/10181/6285624/RDC\\_519\\_2021\\_.pdf/0a0f583f-9fd7-43ee-a2dc-1a155232cced](http://antigo.anvisa.gov.br/documents/10181/6285624/RDC_519_2021_.pdf/0a0f583f-9fd7-43ee-a2dc-1a155232cced)

Brazilian Health Regulatory Agency (Anvisa)  
SIA, Trecho 5, Área Especial 57  
Brasília – DF / Brazil  
CEP: 71.205-050  
Phone.: +(55) 61 3462.5402  
Website: [www.anvisa.gov.br](http://www.anvisa.gov.br)