

NOTIFICATION

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

<p>1. Notifying Member: <u>Brazil</u> If applicable, name of local government involved (Articles 3.2 and 7.2):</p>
<p>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:</p> <p>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</p>
<p>3. Notified under Article 2.9.2 [], 2.10.1 [X], 5.6.2 [], 5.7.1 [], other:</p>
<p>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</p> <p>HS Code(s): 300220 (Vaccines for human medicine).</p>
<p>5. Title, number of pages and language(s) of the notified document: Resolution – RDC number 465, February 9th, 2021. Language(s): Portuguese. Number of pages: 4.</p>
<p>6. Description of content: This Resolution establishes the exemption of market authorization and emergency use authorization and the procedure for the import and monitoring of Covid-19 vaccines acquired by the Ministry of Health within the scope of The Global Alliance for Vaccines and Immunization Covid-19 (Covax Facility) for the tackling the Public Health Emergency of National Concern related to the new coronavirus pandemic (SARS-CoV-2).</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.</p> <p>Public health emergency of national importance due to the outbreak of the new coronavirus (SARS-CoV-2).</p>
<p>8. Relevant documents: 1) Brazilian Official Gazette 27-A on 09 February 2021, section 1 Extra A, page 1.</p> <p>https://www.in.gov.br/web/dou/-/resolucao-rdc-n-465-de-9-de-fevereiro-de-2021-303002180</p>
<p>9. Proposed date of adoption: In the date of its publication.</p> <p>Proposed date of entry into force: 09 February 2021</p>

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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http://antigo.anvisa.gov.br/documents/10181/6226224/RDC_465_2021_.pdf/ffc79c3d-7872-44df-ae8c-96f40094af7a

<https://www.in.gov.br/web/dou/-/resolucao-rdc-n-465-de-9-de-fevereiro-de-2021-303002180>