

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 [X], 2.10.1 [], 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>Medical Devices (HS – 9018)</p>
<p>5. Title, number of pages and language(s) of the notified document: Draft Resolution No. 1049, 27 May 2021. Language(s): Portuguese. Number of pages: 11.</p> <p>Draft: http://antigo.anvisa.gov.br/documents/10181/6279684/CONSULTA+P%C3%9ABLICA+N+1049+GGTPS.pdf/84c0e023-ae93-4835-8172-3c36f6ba806e</p> <p>Comment form: https://pesquisa.anvisa.gov.br/index.php/918276?lang=pt-BR</p>
<p>6. Description of content:</p> <p>This Resolution has the objective of defining the requirements for the approval of programs of "compassionate" use of medical devices.</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health</p>
<p>8. Relevant documents: 01) Brazilian Official Gazette 103 on 02 June 2021, section 1, page 120 02) Regulatory Impact Analysis (RIA) dispensation motivations</p> <p>https://www.in.gov.br/web/dou/-/consulta-publica-n-1.049-de-27-de-maio-de-2021-323576399</p> <p>http://antigo.anvisa.gov.br/documents/10181/6279684/Parecer+com+as+motiva%C3%A7%C3%B5es+de+dispensa+de+AIR.pdf/865ee3d7-91a6-4e4d-8cc6-99d2149f74e8</p>

9. Proposed date of adoption: To be defined

Proposed date of entry into force: to be defined

10. Final date for comments: 23/07/2021

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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