NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** BRAZIL  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **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:**  National Institute of Metrology, Quality and Technology (INMETRO)  Telephone: +(55) 21 2145.3817  Telefax: +(55) 21 2563.5637  Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)  Web-site: [www.inmetro.gov.br/barreirastecnicas](http://www.inmetro.gov.br/barreirastecnicas) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Pharmaceutical goods specified in Note 4 to this Chapter. (HS code(s): 3006) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution number 700, 13 May 2022; (12 page(s), in Portuguese) |
| **6.** | **Description of content:** This Resolution contains provisions on products with antimicrobial action used in critical and semi-critical articles, and their market authorization.  This Resolution incorporates the GMC MERCOSUR Resolution number 19/2010. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This Resolution aims to define, classify and regulate the conditions for market registration and labeling for products with antimicrobial action for use in health care for critical and semi-critical items to be marketed.; Protection of human health or safety |
| **8.** | **Relevant documents:**  The GMC MERCOSUR Resolution number 19/2010 (<https://normas.mercosur.int/public/normativas/1825>) |
| **9.** | **Proposed date of adoption:** 1 June 2022  **Proposed date of entry into force:** 1 June 2022 |
| **10.** | **Final date for comments:** Not Applicable |
| **11.** | **Texts available from: National enquiry point [****]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  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)  The final text is available only in Portuguese and can be downloaded at:  <http://antigo.anvisa.gov.br/documents/10181/6437935/RDC_700_2022_.pdf/150cff23-a531-4fb7-ab7a-4337f2da3f04> |