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 2145.3817Telefax: +(55) 21 2563.5637Email: barreirastecnicas@inmetro.gov.brWeb-site: 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):** Medical equipment (ICS code(s): 11.040) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft resolution 1200, 01 September 2023; (6 page(s), in Portuguese) |
| **6.** | **Description of content:** This Draft Resolution contains provisions on the establishment of an optimized procedure for the analysis and decision of requests for registration of medical devices, through the use of analyzes carried out by an Equivalent Foreign Regulatory Authority.For the purposes of adopting the optimized analysis procedure, the following AREE andrespective proof of registration or authorization:I - Australia: Australia Therapeutic Goods Administration (TGA) – Australian Register of TherapeuticGoods (ARTG);II - Canada: Health Canada (HC) – Medical Device License;III - Japan: Japan Ministry of Health, Labor and Welfare (MHLW) – Pre-market approval (Shonin) fromMHLW; It isIV - United States of America (USA): US Food and Drug Administration (US FDA) – 510KClearance or Premarket Approval (PMA). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This draft resolution aims at providing instruments for the construction process of regulatory trust with other Foreign Regulatory Authorities, in addition to being convergent with international practices and promotes the use of tools for mutual recognition of processes medical device regularization toilets.; Protection of human health or safety |
| **8.** | **Relevant documents:** - |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 25 September 2023; The short comment period occurs because it is a low regulatory impact norm. |
| **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 57Brasília – DF / BrazilCEP: 71.205-050Phone.: +(55) 61 3462.5402Website: www.anvisa.gov.brThe final text is available only in Portuguese and can be downloaded at:Draft: [http://antigo.anvisa.gov.br/documents/10181/6649665/consulta\_+publica\_1200\_2023+SGCOL+DP+.pdf/2c4f52c0-762f-4028-b17f-c4aa621e1ef6](http://antigo.anvisa.gov.br/documents/10181/6649665/consulta_%2Bpublica_1200_2023%2BSGCOL%2BDP%2B.pdf/2c4f52c0-762f-4028-b17f-c4aa621e1ef6) Comment form: <https://pesquisa.anvisa.gov.br/index.php/922864?lang=pt-BR> The comment form link will be available only on 11 September 2023.<https://members.wto.org/crnattachments/2023/TBT/BRA/23_12219_00_x.pdf> |