NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **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.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 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** HS (9018) – medical devices; Instruments and appliances used in medical, surgical, dental or veterinary sciences, incl. scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments, n.e.s (HS 9018) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution 542, 30 August 2021. Language: Portuguese. Number of Pages: 1.  (1 page(s), in Portuguese) |
| **6.** | **Description of content:** This resolution defines "group of products" to which item 5.3 of Annex II of Law 9.782, 26 January 1999, applies. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health. ; Protection of human health or safety |
| **8.** | **Relevant documents:** Law 9.782, 26 January 1999<http://www.planalto.gov.br/ccivil_03/leis/l9782.htm> |
| **9.** | **Proposed date of adoption:** 1 October 2021**Proposed date of entry into force:** 1 October 2021 |
| **10.** | **Final date for comments:** Not applied. |
| **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.br](http://www.anvisa.gov.br)<http://antigo.anvisa.gov.br/documents/10181/6319545/RDC_542_2021_.pdf/49c04a5b-7b22-4d51-8094-936c0306f2e2> |