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 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** 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); Apparatus based on the use of X-rays or of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, incl. radiography or radiotherapy apparatus, X-ray tubes and other X-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like (HS 9022) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Resolution number 1051, 28 June 2021 (2 page(s), in Portuguese) |
| **6.** | **Description of content:** Draft Resolution No. 1051 disposes the positive identification of medical devices regulated at Anvisa, through the Unique Identification of Medical Devices (UDI) system.  Comment form: <https://pesquisa.anvisa.gov.br/index.php/931146?lang=pt-BR> |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The UDI system aims to provide a simple and globally harmonic positive identification of medical devices through distribution and use, requiring the device label to accept a unique global device identifier (to be expressed by Automatic Identification Data Capture and, if applicable, Human Readable Interpretation) based on a standard: the UDI-DI of that unique global identifier being linked to a UDI database of a specific jurisdiction; Protection of human health or safety |
| **8.** | **Relevant documents:** 01) Brazilian Official Gazette 121 on 30 June 2021, section 1, page 161; 02) RIA dispensation motivations  <https://www.in.gov.br/web/dou/-/resolucao-rdc-n-521-de-23-de-junho-de-2021-329125498>  [<http://antigo.anvisa.gov.br/documents/10181/6292482/Parecer+-+Dispensa+de+AIR/50a0b7ff-25d0-4b5d-bacc-531992f9a1a3>](http://antigo.anvisa.gov.br/documents/10181/6292482/Parecer+-+Dispensa+de+AIR/50a0b7ff-25d0-4b5d-bacc-531992f9a1a3) |
| **9.** | **Proposed date of adoption:** Not applied  **Proposed date of entry into force:** Not applied |
| **10.** | **Final date for comments:** 6 September 2021 |
| **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)  <http://antigo.anvisa.gov.br/documents/10181/6292482/%281%29CONSULTA+P%C3%9ABLICA+N+1051+GGTPS.pdf/a56dfa95-a61c-4680-8ebe-2bb40d05508e> |