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):** HS (3006) - Medical devices |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution – RDC number 657, 24 March 2022; (10 page(s), in Portuguese) |
| **6.** | **Description of content:** This resolution contains provisions on the regularization of software as a medical device (Software as a Medical Device - SaMD).The Medical Devices Technical Dossier Structure is aligned with the document issued by the International Medical Device Regulators Forum - IMDRF/RPS WG/N9 (Edition 3) |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** - |
| **9.** | **Proposed date of adoption:** 1 July 2022**Proposed date of entry into force:** 1 July 2022 |
| **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://antigo.anvisa.gov.br/documents/10181/5141677/RDC_657_2022_.pdf/f1c32f0e-21c7-415b-8b5d-06f4c539bbc3> |