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:**  National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)  Web-site: [www.inmetro.gov.br/barreirastecnicas](http://www.inmetro.gov.br/barreirastecnicas)  **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:**  Brazilian Health Regulatory Agency (ANVISA) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****X],** **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 Code(s): medical devices (2936, 2937, 3001, 3002, 3003, 3004, 3006) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution – RDC number 375, 17 April 2020 (2 page(s), in Portuguese) |
| **6.** | **Description of content:** This resolution extraordinarily and temporarily establishes the submission procedure for clinical studies required to validate medical devices of Classes III and IV identified as essential to healthcare services, due to the international public health emergency related to the SARS-CoV-2. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** Published in the Brazilian Official Gazete 74 - B, of 17 April 2020, section 1 - Extra, page 2 |
| **9.** | **Proposed date of adoption:** On the date of publication of the final text  **Proposed date of entry into force:** On the date of publication of the final text |
| **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)  <http://portal.anvisa.gov.br/documents/10181/5809525/RDC_375_2020_.pdf/41f213d1-a7a2-4eb8-932d-16ecb65d51ea> |