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 2145.3817 Telefax: +(55) 21 2563.5637 Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)  Website: [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):** Vaccines for human medicine (HS 300220) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution - RDC n. 533, August 24th, 2021. (4 page(s), in Portuguese) |
| **6.** | **Description of content:** This Resolution establishes exceptional procedures and temporary for import of vaccines COVID-19 regularized at ANVISA and its supplies for the tackling the Public Health Emergency of National concern related to the new coronavirus pandemic (SARS–CoV -2) |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Public health emergency of national importance due to the outbreak of the coronavirus (SARS – CoV – 2); Protection of human health or safety |
| **8.** | **Relevant documents:** Not applied |
| **9.** | **Proposed date of adoption:** On the date of its publication  **Proposed date of entry into force:** On the date of its publication |
| **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 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/10181/6316510/RDC_533_2021_.pdf/abdae9f3-7446-4f0b-899a-25b7c7aea087> |