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.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 (3003, 3004, and 3006) – Medicaments and Medical devices |
| **5.** | **Title, number of pages and language(s) of the notified document:** Ordinance number 538, 15 October 2021 (1 page(s), in Portuguese) |
| **6.** | **Description of content:** This ordinance delegates competence to carry out inspections to verify compliance with the Good Manufacturing Practices of manufacturers of health products of risk class III and IV and medicines, except medicinal gases, for the purpose of issuing the Operating Permit and the Certificate of Good Manufacturing Practices. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** Not applicable |
| **9.** | **Proposed date of adoption:** In the date of its publication (15 October 2021)**Proposed date of entry into force:** In the date of its publication (15 October 2021) |
| **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 57Brasília – DF / BrazilZIP CODE: 71.205-050Phone.: +(55) 61 3462.5402Website: [www.anvisa.gov.br](http://www.anvisa.gov.br)<https://www.in.gov.br/en/web/dou/-/portaria-pt-n-538-de-15-de-outubro-de-2021-353049646> |