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:**  The Brazilian Health Regulatory Agency |
| **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): 2941; 3002300; 3003; 3004; 3005; (pharmaceutical products, in vitro diagnosis products, biological products |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution – RDC number 348, 17 March 2020 (7 page(s), in Portuguese) |
| **6.** | **Description of content:** This resolution establishes exceptional and temporary criteria and procedure for the processing of petitions for the market authorization of medicines, biological products, and in vitro diagnosis products; and for the post-market authorization of medicines and biological products due to the international public health emergency of the new coronavirus (Covid-19). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health |
| **8.** | **Relevant documents:** (1) Brazilian Official Journal (Diário Oficial da União) 53, 18 March 2020, section 1, page 59; (2) Not informed. (3) Brazilian Official Journal (Diário Oficial da União); (4) Not informed. |
| **9.** | **Proposed date of adoption:** In the date of its publication.  **Proposed date of entry into force:** In the date of its publication. |
| **10.** | **Final date for comments:** Not applied. |
| **11.** | **Texts available from: National enquiry point [****X]** **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/10181/5815062/RDC_348_2020_.pdf/ea3791b2-ca73-4ae9-83b8-1882f1e80662> |