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:** National Institute of Metrology, Quality and Technology (INMETRO)Telephone: +(55) 21 2145.3817Email: 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 [****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 Code(s): 2106, 29, 2936, 2937, 2941, 3303, 3304, 3305, 3306, 3307, 340111, 340130, 3402, 340119, 340120, 330290, 9616, 9619 |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Resolution number 805, 27 March 2020 (9 page(s), in Portuguese)Comment form: http://formsus.datasus.gov.br/site/formulario.php?id\_aplicacao=54824  |
| **6.** | **Description of content:** This resolution establishes administrative procedure for the concession of Good Manufacturing Practices Certification for medicines, medical devices, personal hygiene products, cosmetics, perfumes, sanitizers, active pharmaceutical ingredients, and food; and Good Practices of Storage and Distribution Certification for medicines, medical devices, and active pharmaceutical ingredients. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health |
| **8.** | **Relevant documents:** (1) Brazilian Official Gazette (Diário Oficial da União) 63, 01 April 2020, section 1, page 103; (2) Not stated; (3) Brazilian Official Gazette; (4) Not stated. |
| **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:** 5 August 2020 |
| **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 57Brasília – DF / BrazilCEP: 71.205-050Phone.: +(55) 61 3462.5402Website: [www.anvisa.gov.br](http://www.anvisa.gov.br)[http://portal.anvisa.gov.br/documents/10181/5833170/CP+805.pdf/ab194b8c-fb14-473d-aa00-9035b6ad93a7](http://portal.anvisa.gov.br/documents/10181/5833170/CP%2B805.pdf/ab194b8c-fb14-473d-aa00-9035b6ad93a7) |