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 2563.2918  Telefax: +(55) 21 2563.5637  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 [****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 Codes: 2941; 30. |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution - RDC number 283, 17 May 2019. Published on D.O.U, 22 May 2019, pages 61-62. (5 page(s), in Portuguese) |
| **6.** | **Description of content:** This resolution establishes technical requirements for investigation, control and elimination of nitrosamines potentially carcinogenic in active pharmaceutical ingredients (IFA) which are angiotensin II receptor antagonists; and is applied to companies that manufacture, import and fractionate active pharmaceutical ingredients (IFA). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health |
| **8.** | **Relevant documents:**   * Resolution - RDC number 166, 24 July 2017. |
| **9.** | **Proposed date of adoption:** 22 May 2019  **Proposed date of entry into force:** 22 May 2019 |
| **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/10181/5504465/RDC_283_2019_.pdf/7edb158b-6069-4a56-a2f1-874cbefbc248> |