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 2563.2765Telefax: +(55) 21 2563.5637Email: 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):** Certification of Good Manufacturing Practices and Certification of Good Distribution Practices and/or Storage. |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution – RDC n. 179, 27 September 2017. Portuguese.  |
| **6.** | **Description of content:** This Resolution amends the Resolution - RDC No. 39, of 14 August 2013. Art. 4 of the Resolution - RDC No. 39 of 2013, which provides for administrative procedures to grant Certification of Good Manufacturing Practices and Certification of Good Distribution and/or Storage Practices, shall be in force with the following wording: "Art. 4 - .................................Anvisa may use confidential information on inspections received under Agreements or Agreements with health authorities of other countries to subsidize the granting of the certification referred to in the caput of this article." (NR)It includes Art. 4-A in the Resolution - RDC No. 39, of 2013, with the following wording:"Article 4-A - For Health Products, the concession of the Certification of Good Manufacturing Practices referred to in the caput of article 4, regarding establishments located outside the national territory and Mercosur, may occur, at the discretion of the Anvisa:I - from results of inspections carried out by Anvisa in loco;II - upon presentation of a valid audit report attesting to the effective compliance with the technical regulation of Good Manufacturing Practices for Medical Products and Products for Diagnosis of In Vitro use, as set forth in Resolution RDC No. 16 of 28/03/2013 and its updates, issued by a third auditor, according to specific programs, both recognized by Anvisa;III - upon evaluation of technical documents requested by Anvisa related to the quality assurance system of the company and to the verification of compliance with Good Manufacturing Practices issued by the sanitary authority of the country of origin or by a third auditing body accredited by it, as will be established in Normative Instruction to be published by Anvisa."Art. 5 of the Resolution - RDC No. 39, of 2013, shall become effective with the following wording:"Article 5 - .................................Anvisa may establish exceptions to the provisions of the caput of this article, in favour of the efficiency and optimization of resources related to international inspections, according to previously defined criteria." (NR)This Resolution revokes the Resolution - RDC No. 15, dated 28 March 2014, published in the Official Gazette of the Union of 31 March 2014. |
| **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) Nº 189, 2 October 2017, section 1, pages 55; (2) Law 9.782, 26 January 1999; Resolution RDC 61, 3 February 2016 (3) Brazilian Official Journal; (4) Not applicable  |
| **9.** | **Proposed date of adoption:**2 September 2017**Proposed date of entry into force:**2 September 2017 |
| **10.** | **Final date for comments:** Not applicable |
| **11.** | **Texts available from: National enquiry point [****X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** <http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=55&data=02/10/2017> |