



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Notifying Member: <u>Brazil</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: The Brazilian Health Regulatory Agency 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 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
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, March 17 th , 2020. Language(s): Portuguese. Number of pages: 7. Resolution: http://portal.anvisa.gov.br/documents/10181/5815062/RDC_348_2020_.pdf/ea3791b2-ca73-4ae9-83b8-1882f1e80662
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: Not applied.
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:

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