WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade Original:

NOTIFICATION

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

1.	**Notifying Member:** Brazil **If applicable, name of local government involved (Articles 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 2563.2918 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: 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):** HS Code(s): 3002300, 3822 (In vitro diagnosis products)
5.	**Title, number of pages and language(s) of the notified document:** Draft resolution number 734, October 22nd, 2019. **Number of pages:** 20; **Language(s):** Portuguese. Draft: http://portal.anvisa.gov.br/documents/10181/5673188/CONSULTA+P%C3%9ABLICA+N%C2%B0+734+GGTPS/137a0358-a9b1-4bb1-b8c2-5cbcf677f570 Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=51499
6.	**Description of content:** This draft resolution proposes the updating of the Resolution – RDC number 36, August 26th, 2015, which establishes the risk classification, control scheme of notification, registration, market authorization and technical requirements for labelling and usage instructions of medical devices for in vitro diagnosis.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health.
8.	**Relevant documents:** Resolution – RDC number 36, August 26th, 2015
9.	**Proposed date of adoption:** To be determined after the end of the consultation period. **Proposed date of entry into force:** 60 days after the date of its publication.
10.	**Final date for comments:** December 30th, 2019
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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