WORLD TRADE ORGANIZATION

G/TBT/N/BRA/857

4 January 2019

(19-0027)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

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 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: 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) http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=28757
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):** Advanced investigational therapy
5.	**Title, number of pages and language(s) of the notified document:** Resolution of The Collegiate Board of Directors RDC 260, 28 December 2018 published by Brazilian Official Gazette (5 page(s), in Portuguese)
6.	**Description of content:** This Resolution establishes the rules for conducting clinical trials with product of advanced investigational therapy in Brazil and gives other measures. This Resolution applies to clinical trials with product of advanced investigational therapy, which will be developed in Brazil, for safety verification, efficacy or efficacy and safety purposes. Registration and post-registration of products of advanced therapy should follow specific regulations. This Resolution does not apply to: • Clinical trials with medicaments regarding RDC 9, 20 February 2015 or its updates; and • Clinical trials with medical devices regarding RDC 10, 20 February 2015 or its updates This Resolution also establishes the responsibilities of sponsor and research-sponsor and general requirements for submission to Anvisa.

7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety
8.	**Relevant documents:** Not applicable
9.	**Proposed date of adoption:** On the date of its publication. **Proposed date of entry into force:** 60 days counted from the date of its publication
10.	**Final date for comments:** Not applicable
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Agency Responsible 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.in.gov.br/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/57218930/do1-2018-12-28-resolucao-da-diretoria-colegiada-rdc-n-260-de-21-de-dezembro-de-2018-57218634