



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: 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): 30022000 (Vaccines).
5. Title, number of pages and language(s) of the notified document: Resolution – RE number 3076, October 31 st , 2019. Number of pages: 1; Language(s): Portuguese.
6. Description of content: This resolution establishes the technical requirements for the influenza vaccines commercialization from February 2020. The influenza trivalent vaccine must contain, necessarily, three types of combined virus strains, and be according to specifications described below: - a virus similar to influenza A/Brisbane/02/2018 (H1N1)pdm09 virus; - a virus similar to virus influenza A/South Australia/34/2019 (H3N2) virus; and - a virus similar to virus influenza B/Washington/02/2019 (strain B/Victoria) virus.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health.
8. Relevant documents: Resolution – RE number 2735, October 2nd, 2019
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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<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=01/11/2019&jornal=515&pagina=148>