



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 2145.3817 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): 4015100, 650610, 900490, 90200 (personal protective equipment)
5. Title, number of pages and language(s) of the notified document: Resolution number 444, 10 December 2020. Language(s): Portuguese. Number of pages: 11. http://antigo.anvisa.gov.br/documents/10181/6156982/RDC_448_2020_.pdf/7daf7838-fb07-4a1f-8b7d-5425df7c2ccd
6. Description of content: This resolution establishes temporary and extraordinary requirements for the fabrication, importation and commercialization of personal protective equipment identified as priority for use at health services, due to the Public Health Emergency of International Concern related to the SARS-CoV-2 pandemic.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health. According to market monitoring and surveillance data, it was found the difficulty in supervising the compliance with RDC No. 356 of 20 and acting consistently in ensuring the quality, safety and efficacy of products in circulation in the national market. In addition, several companies have expressed concern about the possible expiry of RDC No. 356 of 20, amended by 379 of 20, to the effect of the period necessary for depletion of stock of products manufactured or imported under the exceptionality regime. Thus, in order to increase regulatory predictability, it is suggested the definition of a deadline for exhaustion of the remaining stock of 120 days for products manufactured or imported, after the end of the term of the Resolution.
8. Relevant documents: 1) Brazilian Official Gazette 241 on 17 December 2020, section 1,

page 171 https://www.in.gov.br/web/dou/-/resolucao-rdc-n-448-de-15-de-dezembro-de-2020-294648890	
9.	Proposed date of adoption: On the day of its publication Proposed date of entry into force: On the day of its publication
10.	Final date for comments:
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: 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