



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): 9022, 90181210, 90181300, 90229090, 90189090 (radiography systems, interventional radiology, fluoroscopy system, magnetic resonance system, ultrasound system, mammography system, tomography system)
5. Title, number of pages and language(s) of the notified document: Normative Instruction number 78, 18 November 2020. Number of Pages: 30. Language(s): Portuguese. Normative Instruction: http://antigo.anvisa.gov.br/documents/10181/6126149/IN_78_2020_.pdf/4b5fa443-5d2c-45c7-a963-8403dbeae0e8
6. Description of content: This Normative Instruction changes the Normative Instructions from number 52 to 59, 20 December 2019.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: 1) Brazilian Official Gazette 225 on 25 November 2020, section 1, page 155 2) Normative Instruction Nº 52 3) Normative Instruction Nº 53 4) Normative Instruction Nº 54 5) Normative Instruction Nº 55 6) Normative Instruction Nº 56 7) Normative Instruction Nº 57 7) Normative Instruction Nº 58 8) Normative Instruction Nº 59. https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-78-de-18-de-novembro-de-2020-290045915 Normative Instruction number 52, December 20th, 2019

Normative Instruction number 53, December 20th, 2019 Normative Instruction number 54, December 20th, 2019 Normative Instruction number 55, December 20th, 2019 Normative Instruction number 56, December 20th, 2019 Normative Instruction number 57, December 20th, 2019 Normative Instruction number 58, December 20th, 2019 Normative Instruction number 59, December 20th, 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: 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