



14 September 2021

(21-6803)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>BRAZIL</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Brazilian Health Regulatory Agency (ANVISA) <b>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:</b> National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Telefax: +(55) 21 2563.5637 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> HS (3002, 3006) - devices of single-use transfusion, gravitational infusion, and infusion for using with an infusion pump
<b>5. Title, number of pages and language(s) of the notified document:</b> Resolution 539, 30 August 2021. Language: Portuguese. Number of Pages: 6. <a href="http://antigo.anvisa.gov.br/documents/10181/6319545/RDC_539_2021_.pdf/3b905bd2-5749-491c-9972-93756c1d38b0">http://antigo.anvisa.gov.br/documents/10181/6319545/RDC_539_2021_.pdf/3b905bd2-5749-491c-9972-93756c1d38b0</a> (6 page(s), in Portuguese)
<b>6. Description of content:</b> This resolution establishes minimum identity and quality requirements for devices of single-use transfusion, gravitational infusion, and infusion for using with an infusion pump.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety
<b>8. Relevant documents:</b> Not applied.
<b>9. Proposed date of adoption:</b> 1 October 2021 <b>Proposed date of entry into force:</b> 1 October 2021
<b>10. Final date for comments:</b> Not applied.

**11. Texts available from: National enquiry point [ ] 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](http://www.anvisa.gov.br)