



Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated, is being circulated at the request of the delegation of Brazil.

Title: Medical Devices Subject to the Health Surveillance System

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input checked="" type="checkbox"/>	Notified measure published - date: 21 December 2020
<input checked="" type="checkbox"/>	Notified measure enters into force - date: 28 December 2020
<input checked="" type="checkbox"/>	Text of final measure available from ¹ : https://www.in.gov.br/en/web/dou/-/portaria-n-384-de-18-de-dezembro-de-2020-295233211 http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC002684.pdf
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input type="checkbox"/>	Content or scope of notified measure changed New deadline for comments (if applicable):
<input type="checkbox"/>	Interpretive guidance issued and text available from ¹ :
<input type="checkbox"/>	Other:

Description: National Institute of Metrology, Quality and Technology – Inmetro, issued the Inmetro Ordinance 384, 18 December 2020 that approves the Conformity Assessment and the Specifications for the Conformity Identification Seal for Equipment under the Health Surveillance Regime - Consolidated, established, respectively, in Annexes I and II.

Inmetro Ordinance Nº 384 revokes the Inmetro Ordinances:

I - Nº 350, 6 September 2010, published in the Federal Official Gazette on 9 September 2010, section 01, page 67, on 30 April 2023;

II - Nº 54, 1 February 2016, published in the Federal Official Gazette on 2 February 2016, section 01, pages 70 to 71, within 6 (six) months from the effective date of this Ordinance;

¹ This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final measure and/or interpretive guidance can be obtained.

III - Nº 544, 24 November 2016, published in the Federal Official Gazette on 29 November 2016, section 01, page 41, within 6 (six) months from the effective date of this Administrative Rule.