



NOTIFICATION

Addendum

The following communication, dated 14 May 2021, 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: 14 June 2021
<input checked="" type="checkbox"/>	Notified measure enters into force - date: 14 June 2021
<input checked="" type="checkbox"/>	Text of final measure available from ¹ : https://www.in.gov.br/en/web/dou/-/portaria-inmetro-n-254-de-9-de-junho-de-2021-325397591 http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC002774.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	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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 Ordinance No. 254, 09 June 2021, that amends Inmetro Ordinance No. 384 of 2020, which consolidates the conformity assessment requirements for equipment under sanitary surveillance system.

Inmetro Ordinance No. 254 revokes on the effective date of adoption:

- Ordinance Inmetro No. 54, 1 February 2016, published in the Official Gazette of 2 February 2016, Section 1, pages 70 to 71, within 36 (thirty-six) months from the effective date of this Ordinance; and

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.

- Ordinance Inmetro No. 544, of 24 November 2016, published in the Official Gazette of 29 November 2016, Section 1, page 41, within 36 (thirty-six) months from the effective date of this Ordinance." (NR)