

NOTIFICATION

Addendum

The following communication, dated 17 March 2021, is being circulated at the request of the delegation of Brazil.

Title: Resolution – RDC number 478, March 12th, 2021

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: 17 March 2021
<input checked="" type="checkbox"/>	Notified measure enters into force - date: 1 April 2021
<input checked="" type="checkbox"/>	Text of final measure available from ¹ : https://www.in.gov.br/web/dou/-/resolucao-rdc-n-478-de-12-de-marco-de-2021-309012625 http://antigo.anvisa.gov.br/documents/10181/4247877/RDC_478_2021_.pdf/294efeb7-32cd-43d1-b770-f4e577b62c22
<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	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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): Not applicable
<input type="checkbox"/>	Interpretive guidance issued and text available from:
<input type="checkbox"/>	Other:

Description:

The Draft Resolution number 876, 23 July 2020 – previously notified through G/TBT/N/BRA/1070 – which establishes the economic monitoring for medical devices, was adopted as Resolution – RDC number 478, 12 March 2021.

The final text is available only in Portuguese and can be downloaded at:

http://antigo.anvisa.gov.br/documents/10181/4247877/RDC_478_2021_.pdf/294efeb7-32cd-43d1-b770-f4e577b62c22