



NOTIFICATION

Addendum

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

Title: Regularization process of medical devices at ANVISA, pursuant to the Collegiate Board Resolution - RDC No. 340, of March 6, 2020

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input type="checkbox"/>	Notified measure published - date:
<input type="checkbox"/>	Notified measure enters into force - date:
<input type="checkbox"/>	Text of final measure available from ¹ :
<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	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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 checked="" type="checkbox"/>	Other: https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-74-de-16-de-setembro-de-2020-278150638 http://antigo.anvisa.gov.br/legislacao#/visualizar/433080

Description: The Normative Instruction number 61, 6 March 2020 – previously notified through [G/TBT/N/BRA/940/Add.1](#) – which establishes the topics for the changing of information presented in the process of market authorization of medical devices in ANVISA, was changed by the Normative Instruction number 74, 16 September 2020.

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.