WORLD TRADE ORGANIZATION

G/TBT/N/BRA/1029/Add.1

[date]

(xx-xxx)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

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

Title: Process of regularization of medical devices. RDC 431, 13 October 2020.

Reason for Addendum:	
[ ]	Comment period changed - date:
[X]	Notified measure adopted - date: 13 October 2020
[ ]	Notified measure published - date:
[X]	Notified measure enters into force - date: 01 November 2020
[ ]	Text of final measure available from[1]: http://antigo.anvisa.gov.br/documents/10181/5916206/RDC_431_2020_.pdf/5a85aaec-f1d2-4735-826a-33ccd6e74446
[ ]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
[ ]	Content or scope of notified measure changed New deadline for comments (if applicable):
[ ]	Interpretive guidance issued and text available from[1]:
[ ]	Other:

Description: Draft Resolution number 823, 12 June 2020 – previously notified through G/TBT/N/BRA/1029 – which establishes technical requirements for the inclusion and updating of notification and market authorization form, product image, instructions for use and labelling in the process of regularization of medical devices, was adopted as Resolution – RDC number 431, 13 October 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.