NOTIFICATION

Addendum

The following communication, dated 9 April 2021, is being circulated at the request of the delegation of Brazil.

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**Title:** Resolution – RDC number 489, 08 April 2021

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| **Reason for Addendum:** | |
| [  ] | Comment period changed - date: |
| [  ] | Notified measure adopted - date: |
| [X] | Notified measure published - date: 8 April 2021 |
| [X] | Notified measure enters into force - date: 8 April 2021 |
| [X] | Text of final measure available from[[1]](#footnote-1):  <https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-489-de-7-de-abril-de-2021-312893942>  <http://antigo.anvisa.gov.br/documents/10181/6245812/RDC_489_2021_.pdf/50ae8d42-0a2f-4758-864a-820a52f60827> |
| [  ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [  ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [  ] | Interpretive guidance issued and text available from1: |
| [  ] | Other: |

**Description:** ANVISA issued RDC No. 489, 7 April 2021, that amends the Collegiate Board Resolution - RDC No. 483, of 19 March 2021, previously notified through G/TBT/N/BRA/1154, which provides, in an extraordinary and temporary way, on the requirements for the importation of new medical devices and medicines identified as priorities for use in health services, due to the international public health emergency related to SARS-CoV-2.

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

<http://antigo.anvisa.gov.br/documents/10181/6245812/RDC_489_2021_.pdf/50ae8d42-0a2f-4758-864a-820a52f60827>

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)