NOTIFICATION

Addendum

The following communication, dated 13 September 2021, is being circulated at the request of the delegation of Brazil.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title:** Resolution – RDC number 305, 24 September 2019

|  |
| --- |
| **Reason for Addendum:** |
| [  ] | Comment period changed - date:  |
| [  ] | Notified measure adopted - date:  |
| [  ] | Notified measure published - date:  |
| [  ] | Notified measure enters into force - date:  |
| [  ] | Text of final measure available from[[1]](#footnote-1):  |
| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [X] | Content or scope of notified measure changed and text available from1: <http://antigo.anvisa.gov.br/documents/10181/6320987/RDC_562_2021_.pdf/17968eb3-dcef-4152-b644-5cccacd23f39>New deadline for comments (if applicable):  |
| [  ] | Interpretive guidance issued and text available from1:  |
| [  ] | Other:  |

**Description:** The Resolution number 305, 24 September 2019 - previously notified through G/TBT/N/BRA/842/Add.1 - which disposes about requirements for manufacturing, trading, importing and exposure to the use of personalized medical devices, was changed by Resolution – number 562, 1 September 2021.

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

<http://antigo.anvisa.gov.br/documents/10181/6320987/RDC_562_2021_.pdf/17968eb3-dcef-4152-b644-5cccacd23f39>

**\_\_\_\_\_\_\_\_\_\_**

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)