NOTIFICATION

Addendum

The following communication, dated 12 January 2022, is being circulated at the request of the delegation of Brazil.

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**Title:** Resolution – RDC Nº 283, 17 May 2019 (Amendment)

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| **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| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |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: New deadline for comments (if applicable):  |
| [  ] | Interpretive guidance issued and text available from1:  |
| [  ] | Other:  |

**Description:** Resolution – RDC Nº 283, 17 May 2019 – previously notified through G/TBT/N/BRA/871 – which establishes establishes technical requirements for investigation, control and elimination of nitrosamines potentially carcinogenic in active pharmaceutical ingredients (IFA) which are angiotensin II receptor antagonists; and is applied to companies that manufacture, import and fractionate active pharmaceutical ingredients (IFA), was changed by the Resolution – RDC number 593, 23 December 2021.

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

[http://antigo.anvisa.gov.br/documents/10181/6279847/RDC\_593\_2021\_.pdf/cc6bd605-bdb2-4a8d-94d6-0529ef37ad85](https://webmail.inmetro.gov.br/owa/redir.aspx?C=bvWsU7828RvLlvoEDHGegAb6Dr2SZL8zKZWaO-toeLlxnUREPtXZCA..&URL=http%3a%2f%2fantigo.anvisa.gov.br%2fdocuments%2f10181%2f6279847%2fRDC_593_2021_.pdf%2fcc6bd605-bdb2-4a8d-94d6-0529ef37ad85)

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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)