NOTIFICATION

Addendum

The following communication, dated 1 October 2024, is being circulated at the request of the delegation of Brazil.

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**Title:** Draft Resolution nº 64, August 1st 2014

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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| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |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:  <https://antigo.anvisa.gov.br/documents/10181/6873945/IN_321_2024_.pdf/3c702103-f01e-4d1a-82c5-ee2ed18e1ae4>  <https://members.wto.org/crnattachments/2024/TBT/BRA/modification/24_06383_00_x.pdf>  New deadline for comments (if applicable): |
| [ ] | Interpretive guidance issued and text available from1: |
| [ ] | Other: |

**Description:** Draft Resolution 282, 09 December 2016 - previously notified through G/TBT/N/BRA/601/Add.2 - which contains provisions on inspection procedures for Good Clinical Practices on clinical trials of medical devices, was changed by Normative Instruction 321, 19 September 2024.

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

<https://antigo.anvisa.gov.br/documents/10181/6873945/IN_321_2024_.pdf/3c702103-f01e-4d1a-82c5-ee2ed18e1ae4>

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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)