NOTIFICATION

Addendum

The following communication, dated 10 June 2021, is being circulated at the request of the delegation of Brazil.

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**Title:** ANVISA RDC number 505, 27 May 2021

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| **Reason for Addendum:** | |
| [  ] | Comment period changed - date: |
| [  ] | Notified measure adopted - date: |
| [X] | Notified measure published - date: 31 May 2021 |
| [X] | Notified measure enters into force - date: 1 July 2021 |
| [  ] | 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| [  ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |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://www.in.gov.br/web/dou/-/resolucao-rdc-n-505-de-27-de-maio-de-2021-323002775>  <http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_505_2021_.pdf/43ac298e-1ade-44f0-9f98-22f0b2477255>  New deadline for comments (if applicable): |
| [  ] | Interpretive guidance issued and text available from1: |
| [  ] | Other: |

**Description:** ANVISA issued Resolution RDC number 505, 27 May 2021, which establishes minimum requirements for the registration of an advanced therapy product, with a view to proving its effectiveness, safety and quality for use and commercialization in Brazil. Resolution RDC No. 383 of 20 February 2020 notified through G/TBT/N/BRA/911/Add.1 and Resolution RDC No. 363 of 01 April 2020, notified through G/TBT/N/BRA/911/Add.2 were revoked.

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

<http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_505_2021_.pdf/43ac298e-1ade-44f0-9f98-22f0b2477255>

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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)