



11 June 2021

(21-4805)

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Committee on Technical Barriers to Trade

Original: English

## NOTIFICATION

### Addendum

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

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

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input checked="" type="checkbox"/>	Notified measure published - date: 31 May 2021
<input checked="" type="checkbox"/>	Notified measure enters into force - date: 1 July 2021
<input type="checkbox"/>	Text of final measure available from <sup>1</sup> :
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input checked="" type="checkbox"/>	Content or scope of notified measure changed and text available from <sup>1</sup> : <a href="https://www.in.gov.br/web/dou/-/resolucao-rdc-n-505-de-27-de-maio-de-2021-323002775">https://www.in.gov.br/web/dou/-/resolucao-rdc-n-505-de-27-de-maio-de-2021-323002775</a> <a href="http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_505_2021_.pdf/43ac298e-1ade-44f0-9f98-22f0b2477255">http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_505_2021_.pdf/43ac298e-1ade-44f0-9f98-22f0b2477255</a> New deadline for comments (if applicable):
<input type="checkbox"/>	Interpretive guidance issued and text available from <sup>1</sup> :
<input type="checkbox"/>	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](http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_505_2021_.pdf/43ac298e-1ade-44f0-9f98-22f0b2477255)

<sup>1</sup> 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.