



NOTIFICATION

Addendum

The following communication, dated 19 March 2021, is being circulated at the request of the delegation of Brazil.

Title: Resolution – RDC number 482, 19 March 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: 19 March 2021
<input checked="" type="checkbox"/>	Notified measure enters into force - date: 19 March 2021
<input checked="" type="checkbox"/>	Text of final measure available from ¹ : https://www.in.gov.br/web/dou/-/resolucao-rdc-n-482-de-19-de-marco-de-2021-309557127 http://antigo.anvisa.gov.br/documents/10181/5893706/RDC_482_2021_.pdf/12dc0b32-f1e3-4489-b913-e57a9354e41a
<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	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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 New deadline for comments (if applicable): Not applicable
<input type="checkbox"/>	Interpretive guidance issued and text available from:
<input type="checkbox"/>	Other:

Description:

The Resolution – RDC number 392, 26 May 2020 – previously notified through G/TBT/N/BRA/1032 – which establishes temporary and extraordinary criteria for the application of exceptionalities to specific technical requirements of the Good Manufacturing and Import Practice of Medicinal Products and Active Pharmaceutical Ingredients, due to the international public health emergency of the new coronavirus (Covid-19) – was changed by the Resolution – RDC number 482, 19 March 2021. This resolution establishes exceptionalities for the use of non-medicinal oxygen cylinder, industrial cylinder filling ramps for the filling of medicinal cylinders, and industrial gas filling unit for the filling of medicinal gases.

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

http://antigo.anvisa.gov.br/documents/10181/5893706/RDC_482_2021_.pdf/12dc0b32-f1e3-4489-b913-e57a9354e41a