NOTIFICATION

Addendum

The following communication, dated 26 March 2021, is being circulated at the request of the delegation of Brazil.

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**Title:** Resolution – RDC number 482, 19 March 2021

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| **Reason for Addendum:** |
| [  ] | Comment period changed - date:  |
| [  ] | Notified measure adopted - date:  |
| [X] | Notified measure published - date: 19 March 2021 |
| [X] | Notified measure enters into force - date: 19 March 2021 |
| [X] | Text of final measure available from[[1]](#footnote-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> |
| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [  ] | 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:** The Resolution – RDC number 392, 26 May 2020 – previously notified through [G/TBT/N/BRA/1032](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?MetaCollection=WTO&SymbolList=%22G%2fTBT%2fN%2fBRA%2f1032%22+OR+%22G%2fTBT%2fN%2fBRA%2f1032%2f*%22&Serial=&IssuingDateFrom=&IssuingDateTo=&CATTITLE=&ConcernedCountryList=&OtherCountryList=&SubjectList=&TypeList=&FullTextHash=371857150&ProductList=&BodyList=&OrganizationList=&ArticleList=&Contents=&CollectionList=&RestrictionTypeName=&PostingDateFrom=&PostingDateTo=&DerestrictionDateFrom=&DerestrictionDateTo=&ReferenceList=&Language=ENGLISH&SearchPage=FE_S_S001&ActiveTabIndex=0&HSClassificationList=&ServicesClassificationList=&EnvironmentClassificationList=&ICSClassificationList=&ICSClassificationDescList:EnvironmentClassificationDescList:ServicesClassificationDescList:HSClassificationDescList=&languageUIChanged=true) – 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>

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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)