NOTIFICATION

Addendum

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

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title:** Normative Instruction number 85, establishes technical requirements for medical devices selected to economic monitoring by Anvisa

|  |
| --- |
| **Reason for Addendum:** |
| [  ] | Comment period changed - date:  |
| [  ] | Notified measure adopted - date:  |
| [X] | Notified measure published - date: 17 March 2021 |
| [X] | Notified measure enters into force - date: 1 April 2021 |
| [X] | Text of final measure available from[[1]](#footnote-1): <https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-85-de-12-de-marco-de-2021-308994027><http://antigo.anvisa.gov.br/documents/10181/4247877/IN_85_2021_.pdf/c62ef4d8-6bcd-4ca0-94a9-f57f4e4d938b> |
| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |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 Draft Normative Instruction number 878, 23 July 2020 – previously notified through [G/TBT/N/BRA/1068](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?MetaCollection=WTO&SymbolList=%22G%2fTBT%2fN%2fBRA%2f1068%22+OR+%22G%2fTBT%2fN%2fBRA%2f1068%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 technical requirements for medical devices selected to economic monitoring by Anvisa, was adopted as Normative Instruction number 85, 12 March 2021.

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

<http://antigo.anvisa.gov.br/documents/10181/4247877/IN_85_2021_.pdf/c62ef4d8-6bcd-4ca0-94a9-f57f4e4d938b>

**\_\_\_\_\_\_\_\_\_\_**

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)