

## NOTIFICATION

### *Addendum*

The following communication, dated, 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:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted – date:
<input checked="" type="checkbox"/>	Notified measure published - date: 17 March 2021
<input type="checkbox"/>	Notified measure enters into force - date: 1 April 2021
<input checked="" type="checkbox"/>	Text of final measure available from <sup>1</sup> : <a href="https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-85-de-12-de-marco-de-2021-308994027">https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-85-de-12-de-marco-de-2021-308994027</a> <a href="http://antigo.anvisa.gov.br/documents/10181/4247877/IN_85_2021_.pdf/c62ef4d8-6bcd-4ca0-94a9-f57f4e4d938b">http://antigo.anvisa.gov.br/documents/10181/4247877/IN_85_2021_.pdf/c62ef4d8-6bcd-4ca0-94a9-f57f4e4d938b</a>
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input 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 Draft Normative Instruction number 878, 23 July 2020 – previously notified through G/TBT/N/BRA/1068 – 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](http://antigo.anvisa.gov.br/documents/10181/4247877/IN_85_2021_.pdf/c62ef4d8-6bcd-4ca0-94a9-f57f4e4d938b)