NOTIFICATION

Addendum

The following communication, dated 10 April 2024, is being circulated at the request of the delegation of Brazil.

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**Title:** Draft resolution 1200, 01 September 2023

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| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [X] | Notified measure adopted - date: 3 June 2024 |
| [ ] | Notified measure published - date: |
| [ ] | Notified measure enters into force - date: |
| [ ] | Text of final measure available from[[1]](#footnote-1): |
| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |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:** Draft resolution 1200, 01 September 2023 - previously notified through G/TBT/N/BRA/1500 - which contains provisions on the establishment of an optimized procedure for the analysis and decision of requests for registration of medical devices, through the use of analyzes carried out by an Equivalent Foreign Regulatory Authority, was adopted as Normative Instruction 290, 04 April 2024.

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

<https://antigo.anvisa.gov.br/documents/10181/6649665/IN_290_2024_.pdf/e5960d9a-d41f-4fef-bc7a-12e9aedbd28e>

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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)