NOTIFICATION

Addendum

The following communication, dated 6 May 2024, is being circulated at the request of the delegation of Brazil.

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**Title:** Draft resolution number 1135, 23 December 2022

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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| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |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 number 1135, 23 December 2022 - previously notified through G/TBT/N/BRA/1468 - which is regarded to a regulatory proposal for the establishment of specific criteria and procedures for defining the Equivalent Foreign Regulatory Authorities of the sanitary inspection process of manufacturers of active pharmaceutical ingredients, Cannabis products for medicinal purposes, medicines and biological products, was adopted as Normative Instruction 292, 02 May 2024

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

<https://antigo.anvisa.gov.br/documents/10181/6531690/IN_292_2024_.pdf/33b87ce6-cb6b-4136-b7e8-9adc4d54285d>

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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)