NOTIFICATION

Addendum

The following communication, dated 9 March 2023, is being circulated at the request of the delegation of Brazil.

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**Title:** Draft resolution number 730, 14 October 2019.

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| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [X] | Notified measure adopted - date: 1 March 2023 |
| [ ] | 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| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [X] | Content or scope of notified measure changed and text available from1:  <http://antigo.anvisa.gov.br/documents/10181/5672055/RDC_777_2023_.pdf/de9823a6-80e9-427b-926f-d9651078fcea>  New deadline for comments (if applicable): |
| [ ] | Interpretive guidance issued and text available from1: |
| [ ] | Other: |

**Description:** The Draft resolution number 730, 14 October 2019 (previously notified through [G/TBT/N/BRA/928](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/TBTN19/BRA928.pdf&Open=True)), which proposes the updating of the Resolution – RDC number 185, 22 October 2001, which establishes the risk classification, market authorization and technical requirements for labelling and usage instructions of medical devices, was adopted as Resolution - RDC number 751, 15 September 2022.

Resolution - RDC number 751, 15 September 2022, which provides for risk classification, reporting and registration regimes, and labeling requirements and instructions for use of medical devices, was now modified by Resolution - RDC number 777, 1st March 2023.

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

<http://antigo.anvisa.gov.br/documents/10181/5672055/RDC_777_2023_.pdf/de9823a6-80e9-427b-926f-d9651078fcea>

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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)