WORLD TRADE ORGANIZATION

G/TBT/N/

Date

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Committee on Technical Barriers to Trade Original:

NOTIFICATION

Addendum

The following communication, dated September 26th, 2019, is being circulated at the request of the delegation of Brazil.

The Draft Resolution number 546, September 3rd, 2018 – previously notified through G/TBT/N/BRA/842 – which lays down technical requirements for the manufacturing, marketing, import, export and exposure to use of custom-made and patient specific medical devices and medical devices exempt from registration, was published as Resolution – RDC number 305, September 24th, 2019. This resolution enters into force 30 days after the date of its publication.

We highlight that this Resolution is aligned with what has been agreed in the International Medical Device Regulators Forum (IMDRF).

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

http://portal.anvisa.gov.br/documents/10181/3254343/RDC_305_2019_.pdf/9857315d-e48c-4634-976f-67e1f56f0a99
