



NOTIFICATION

Addendum

The following communication, dated August 22nd, 2019, is being circulated at the request of the delegation of Brazil.

The draft normative instruction regarding Complementary guidelines to the manufacture of sterile medicinal products of the draft resolution number 653, May 24th, 2019 – previously notified through G/TBT/N/BRA/870 - was adopted as a final text, published as Normative Instruction number 35, August 21st, 2019.

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

http://portal.anvisa.gov.br/documents/10181/5389382/IN_35_2019_.pdf/ed82613e-aeb7-47f8-abb3-610bf698a8d2
