



xx October 2015

(xx-xxxx)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated xx October 2015, is being circulated at the request of the delegation of the Brazil.

This addendum aims at informing that the adopted criteria for the conformity assessment program for single use appliances for transfusion, gravitational infusion and infusion for use with infusion pump, under the regime of Sanitary Surveillance, through the mechanism of compulsory certification issued by the National Institute of Metrology, Quality and Technology, notified under the document G/TBT/N/BRA/442/Add.1 (Ordinance 502/2011) was amended by the Ordinance Nº 493, 2 October 2015, due to complains concerning the administration of a cancer drug (cloridrato de doxorrubicina) and the need to take a corrective conformity action by including items 6.1.1.4.1.1.1 and 6.1.1.4.1.3.3 and maintaining the other provisions set by the Inmetro Ordinance Nº 502/2011 as well as the requirements set by the Ordinance RDC Anvisa Nº 4/2011.

The full text of this measure is available in Portuguese and can be downloaded at:

<http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC002314.pdf>