EU DECLARATION OF CONFORMITY

We, Terumo Medical Products(Hangzhou) Co.,Ltd,
M4-9-5 Hangzhou Economic & Technological Development Zone,
310018 Hangzhou, People's Republic of China

With Single Registration Number of（SRN）： CN-MF-000001640

Being the manufacturer of:

BLOOD ADMINISTRATION SET for Infusion Pump

Intended purpose: This product is a single use fitting for intravenous blood administration connecting with the infusion pump. It can also be used for gravity blood administration.
Basic UDI-DI： 69276755PBJ5
Related product codes：See Appendix（full list of active codes）

Declare that the above product of Class IIa is in conformity with applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the "Conformity assessment based on a quality management system and on assessment of technical documentation" set out in Annex IX, and by certification of Annex IX.3（EU quality management system certificate number：G10 037584 0029 Rev.00), under the supervision of [TÜV SÜD Product Service GmbH, Ridlerstraße. 65, 80339 Munich, Germany] as Notified Body authorized by the [Germany] Competent Authority and carrying the Notified Body NO.[0123].

Authorised Representative：TERUMO EUROPE N.V.,
Interleuvenlaan 40,3001 LEUVEN, BELGIUM

This EU declaration of conformity is issued under our sole responsibility.

Hangzhou, 2022.10.14
（Place, Date of Issue）

Yuqing Lin
Person responsible for regulatory compliance
[Terumo Medical Products(Hangzhou) Co.,Ltd]

Appendix：Related product codes

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Brand Name	Model number
TERUFUSION BLOOD ADMINISTRATION SET for Infusion Pump	TB*PU300W
	TB*PU300WY
	TB*PU300SE
	TB*PU300SYE