

Head Office

44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
Telephone: 81-3-3374-8111 Facsimile: 81-3-3374-8399

Rev.03

DECLARATION of CONFORMITY

We, TERUMO Corporation

44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo151-0072 JAPAN

declare under our sole responsibility that the product:

Product : Syringe Infusion Pump

Model/Type : TERUFUSION Syringe Pump Type SS3 OTCI

to which this declaration relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (2014/53/EU).

The product is in conformity with the following standards:

RADIO : EN 300 328 V2.1.1:2016-11

EMC : EN 301 489-1 V2.1.1:2017-02
EN 301 489-17 V3.1.1:2017-02
EN 60601-1-2:2015
EN 60601-2-24:2015

SAFETY : EN IEC 62368-1:2020+A11:2020
EN 62311:2008
EN 60601-1:2006+A11:2011+A1:2013+A12:2014
EN 60601-1-2:2015
EN 60601-1-6:2010+A1:2015
EN 62366-1:2015+AC:2015
EN 60601-1-8:2007+A1:2013+A11:2017
EN 60601-2-24:2015

Conformity test for radio part is performed with Wireless LAN Module (Model: UGFZ1,BP3595)



Date December 16, 2020

Signature : 

Name : Toshio Nakashima

Title : General Manager, Quality Assurance Department



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Object of Declaration

T E * S S □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Digits	Display items	Display
1-2	Product name	TE:TERUFUSION ELECTRICITY
3	Destination	* :For export
4-5	Type	SS :Syringe pump
6-9	Product model	835P :Smart model (RED Applied)
10-11	Power plug shape	01 :- 02 :UK 03 :European

T E - S S □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Digits	Display items	Display
1-2	Product name	TE:TERUFUSION ELECTRICITY
3	Destination	- :For universal (For EMEA)
4-5	Type	SS :Syringe pump
6-8	Product model	835 :Smart model (RED Applied)
9-10	Language of labeling	EN : IFU & LCD English, Nameplate English DE : IFU & LCD German, Nameplate English FR : IFU & LCD French, Nameplate English IT : IFU & LCD Italy, Nameplate English NL : IFU & LCD Dutch, Nameplate English RU : IFU & LCD Russian, Nameplate English ES : IFU & LCD Spanish, Nameplate English PL : IFU & LCD Polish, Nameplate English RO : IFU & LCD Romanian, Nameplate English SK : IFU & LCD Slovak, Nameplate English SV : IFU & LCD Swedish, Nameplate English NO : IFU & LCD Norwegian, Nameplate English FI : IFU & LCD Finnish, Nameplate English HU : IFU & LCD Hungarian, Nameplate English
11	Power plug shape	1: European 2: UK 3: Italy
12	Additional function	P: OTCI function