



**Head Office**

44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan  
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Rev.6

## DECLARATION of CONFORMITY

We, TERUMO Corporation  
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072 JAPAN

declare under our sole responsibility that the product:

**Product : Syringe Infusion Pump**

**Model/Type : TERUFUSION Syringe Pump Type SS**

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 V1.9.2:2011-09  
EN 301 489-17 V2.2.1:2012-09  
EN 60601-1-2:2001/A1:2006  
EN 60601-2-24:1998**

**SAFETY : EN 60950-1:2006+Amd.11:2009+Amd.1:2010+Amd.12:2011+Amd.2:2013  
EN 62479:2010  
EN 60601-1:1990/A1:1993/AC:1994/A2:1995  
EN 60601-1-1:2001  
EN 60601-1-2:2001/A1:2006  
EN 60601-1-4:1996/A1:1999  
IEC 60601-1-4:2000  
EN 60601-1-6:2004  
EN 60601-1-6:2007  
EN 60601-1-8:2004/A1:2006  
EN 60601-1-8:2007  
EN 60601-2-24:1998**

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



Date : June 1, 2017

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 12

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	800N :Smart model
10-11	Power plug shape	01 : - 02 :UK 03 :European (Language of labeling -IFU, LCD, Nameplate- : English) 05 : - (Language of labeling -Nameplate- : English, -IFU, LCD- :Spanish) 07 : - (Language of labeling -IFU, LCD, Nameplate-: Portuguese)
12	Customize	Blank : Not customized S : Modified behavior for Singapore users

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 universal (For EMEA)
4-5	Type	SS :Syringe pump
6-8	Product model	800 :Smart model
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 SV : IFU & LCD Swedish, Nameplate English NO : IFU & LCD Norwegian, Nameplate English DA : IFU & LCD Danish, Nameplate English PL : IFU & LCD Polish, Nameplate English HU : IFU & LCD Hungary, Nameplate English SK : IFU & LCD Slovakia, Nameplate English
11	Power plug shape	1: European 2: UK 3: Italy 4: Danish