TERUMO

No. ME-TFP0750A-006

Rev.04

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

TERUFUSION Syringe Pump
Type SS3

Product : Syringe Infusion Pump

declare that the above products of **Class IIb** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, July 10, 2023
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A: List of product code structure

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 (except for Italy)
4-5	Type	SS :Syringe pump
6-9	Product model	730N :Standard model 732N :Standard External Communication model 830N :Smart model (RED Applied)*1 835N :Smart model (RED Applied)*2 *1 :IEEE802.11b *2 :IEEE802.11b/g/n
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)

Digits	Display items	Display
1-2	Product name	TE:TERUFUSION ELECTRICITY
3	Destination	* :For export (only for Italy)
4-5	Type	SS :Syringe pump
6-8	Product model	730 :Standard model 835 :Smart model (RED Applied)*1 *1 :IEEE802.11b/g/n
9-10	Language of labeling	IT : IFU & LCD Italian, Nameplate English
11	Power plug shape	1 : European

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	730 :Standard model 732 :Standard External Communication model 830 :Smart model (RED Applied)*1 835 :Smart model (RED Applied)*2 *1 :IEEE802.11b *2 :IEEE802.11b/g/n
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