

## DECLARATION OF CONFORMITY

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

being the manufacturer of:

**TERUFUSION Infusion Pump**  
**Type LM3**

**Product : 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, March 18, 2020  
(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION

Appendix A: List of product code structure

T E \* L M □ □ □ □ □ □  
 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	LM :Infusion pump (MID press type)
6-9	Product model	730N :Standard model (Not equipped Anti-free flow system ) 732N : Standard External Communication mode (Not equipped Anti-free flow system ) 730A :Standard model (Equipped Anti-free flow system ) 732A :Standard External Communication model (Equipped Anti-free flow system ) 830A :Smart model (RED Applied)*1 (Equipped Anti-free flow system ) 835A :Smart model (RED Applied)*2 (Equipped Anti-free flow system ) *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)

T E - L M         
 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	LM :Infusion pump (MID press type)
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
12	Anti-free flow system	Blank: Equipped Anti-free flow system N :Not equipped Anti-free flow system