



No.DOC-ME-TFP0730A

Rev.02

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 LF3

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)

A handwritten signature in blue ink, appearing to read "Toshio Nakashima".

Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION



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Appendix A: List of product code structure

T E * L F □ □ □ □ □ □

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	LF :Infusion pump (FULL press type)
6-9	Product model	630N :Standard model 632N :Standard External Communication 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)

T E - L F □ □ □ □ □ □

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	LF :Infusion pump (FULL press type)
6-8	Product model	630 :Standard model 632 :Standard External Communication 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 PL : IFU & LCD Polish, Nameplate English
11	Power plug shape	1: European 2: UK 3: Italy