Rev. 02
[Reference to ME-TDP0680A]

EU DECLARATION OF CONFORMITY

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

being the manufacturer of:

TERUFUSION Rack System

Intended purpose:

TERUFUSION Standard Rack System

The TERUFUSION Standard Rack System, which is intended to be used by healthcare professionals, is a modular system designed to meet the request of a multi-infusion system which combines the advantages of a stacking system (compact and extendable) with those of a racking system (the pumps can be removed or added independently). This modular system allows the use of multiple TERUFUSION Syringe Pump and TERUFUSION Infusion Pump for the same patient with only one power cable.

TERUFUSION Communication Rack System

The TERUFUSION Communication Rack System, which is intended to be used by healthcare professionals, is designed for racking multiple pumps and, provides one-step attaching and detaching of the specified syringe pump and infusion pump, and supplies the AC source to the pump attached. In addition, this product mediates the communication between the pumps or the pump and an external device.

Basic UDI-DI: 498735028RS3S

Related product codes: See Appendix A

declare that the above product of **Class I** is in conformity with the applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and the technical documentation as required by Article 52.7 of the Regulation has been drawn up.

We furthermore declare that the above product is in conformity with the provisions of RoHS Directive (2011/65/EU as amended and applicable) and RED (2014/53/EU) : **See Appendix B.**

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

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There is no reference to Common Specifications that have been used to within the conformity assessment for Regulation (EU) 2017/745.

This EU declaration of conformity is issued under our sole responsibility.

Tokyo , 2021-07-20
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

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Appendix A – Related product codes

＜Regulation (EU) 2017/745 and RoHS Directive＞

Product code									UDI-DI code													
T	E	*	R	S	7	0	0	N	0	4	9	8	7	3	5	0	7	1	1	7	8	6
T	E	*	R	S	8	0	0	N	0	4	9	8	7	3	5	0	7	1	1	8	0	9
T	E	*	R	S	8	1	1	N	0	4	9	8	7	3	5	0	7	1	1	8	2	3
Product code										UDI-DI code												
T	E	*	R	S	8	0	0	N	0	3	0	4	9	8	7	3	5	0	7	1	2	3	0	1

＜RED＞

Product code									UDI-DI code													
T	E	*	R	S	8	0	0	N	0	4	9	8	7	3	5	0	7	1	1	8	0	9
Product code										UDI-DI code												
T	E	*	R	S	8	0	0	N	0	3	0	4	9	8	7	3	5	0	7	1	2	3	0	1

Appendix B – Reference standard of RoHS and RED

＜RoHS Directive＞

EN IEC 63000:2018

＜RED＞

RADIO

EN 300 328 V2.2.2:2019-07

EMC

EN 301 489-1 V2.2.3:2019-11
EN 301 489-17 V3.2.4:2020-09
EN 60601-1-2:2015
EN 60601-2-24:2015

SAFETY

EN 60601-1:2006+A11:2011+A1:2013+A12:2014
EN 60601-1-2:2015
EN 60601-1-6:2010+A1:2015
EN 60601-2-24:2015
EN 62366-1:2015+AC:2015
EN IEC 62368-1:2020+A11:2020
EN 62479:2010

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