TERUMO

No.DOC-KE-PS1SROF

Rev.09

DECLARATION OF CONFORMITY

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

being the manufacturer of:

Versatus

Product : Intravenous Catheter

declare that the above products of **Class IIa** 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, 2 and 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, February 10, 2020
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

Frame No.	Code	
1・2	SR	I.V. Catheter
3	*	for export
4・5	OF	Radio opaque soft catheter
6・7	14	Catheter gauge size 14G
	16	Catheter gauge size 16G
	18	Catheter gauge size 18G
	20	Catheter gauge size 20G
	22	Catheter gauge size 22G
	24	Catheter gauge size 24G
8・9	19	Catheter length 19mm
	25	Catheter length 25mm
	32	Catheter length 32mm
	51	Catheter length 51mm
	64	Catheter length 64mm