TERUMO

No.DOC-PS1SRFF

Rev.09

DECLARATION OF CONFORMITY

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

being the manufacturer of:

Surflash

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

S R	□	F F	□	□	□	□	W
1 2	3	4 5	6	7	8	9	10

1,2 : Product item

SR : I.V. Catheter

3 : Distinction for market

＊ : for export

4,5 : Product type

FF : Radiopaque soft catheter, Catheter flashback detection type

6,7 : Catheter gauge size

14	16	18	20	22	24
14G	16G	18G	20G	22G	24G

8,9 : Catheter length (in millimeter)

19	25	32	51	64
19mm	25mm	32mm	51mm	64mm

10 : Identification of similar products

W : with small wing

Blank : without small wing