TERUMO

No.DOC-PQB-TF-SV1
Rev.09

DECLARATION OF CONFORMITY

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

being the manufacturer of:

SURFLO Winged Infusion Set

Product : Winged Needle

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	SV	Winged intravenous needle
3	*	Export
4・5	18~27	Puncture needle gauge 18G~27G
6	B E	Wing and connector (B : C wing and B connector、E : D wing and B connector)
7	L	Lure taper (connector)
8	S K	Short type (tube length) Gamma rays sterilization products
9	A	Cannula (2527)
10・11	others	01, 02, 03: other types