

EC Declaration of Conformity

We,

Terumo (Philippines) Corporation 124 East Main Avenue, Laguna Technopark Binan, Laguna, Philippines

whose single Authorized Representative:

Terumo Europe N.V Interleuvenlaan 40, 3001 Leuven, Belgium

Being the manufacturer, herewith declare that the products:

Terumo Surflo I.V. Catheter (with the attached product codes)

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

C € 0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD 60147309 0001 Issue date: 2020 – 05 – 01 Expiry date: 2024 – 05 – 26

following the procedure relating to the "EC Declaration of Conformity" set out in Annex VII, combined with the provisions set out in Annex V "Production Quality Assurance" of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of Terumo (Philippines) Corporation

Philippines, 03/19/2~

Place, date of issuance

win Robles

Management Representative

Declaration of Conformity Terumo Surflo IV Catheter List of Product Codes

Radiopaque Catheter Tube

Needle Size Gauge x Length	Product Codes	Lot Number
14G x 2"	SR+OX1451C	051219
	SR+OX1451C3	050614
14G x 2 ½"	SR+OX1464C	050503
	SR+OX1464C1	120319A
16G x 1 1/4"	SR+OX1632C	051125
16G x 2"	SR+OX1651C	051220
	SR+OX1651C1	111020A
	SR+OX1651C3	060106
16G x 2 ½"	SR+OX1664C	051125
	SR+OX1664C1	120512A
18G x 1 1⁄4"	SR+OX1832C	050901
	SR+OX1832C1	120308SA
	SR+OX1832C3	051111
18G x 2"	SR+OX1851C	051109
	SR+OX1851C1	120321SA
	SR+OX1851C3	050614
18G x 2 ½"	SR+OX1864C	051109
	SR+OX1864C1	120221SA
20G x 1"	SR+OX2025C	051109
20G x 1 1⁄4"	SR+OX2032C	050830
	SR+OX2032C1	120404SA
	SR+OX2032C3	051112S
20G x 2"	SR+OX2051C	050902
	SR+OX2051C1	111021SA
	SR+OX2051C3	050606S
22G x 1"	SR+OX2225C	051115
	SR+OX2225C1	120308SB
	SR+OX2225C3	051105
24G x ³ /4"	SR+OX2419C	051104
	SR+OX2419C1	111216SB
	SR+OX2419C3	051111S

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Non- Radiopaque Catheter Tube

Needle Size Gauge x Length	Product Codes	Lot Number
18G x 1 1⁄4"	SR+OT1832C	051116
18G x 2"	SR+OT1851C	050418
20G x 1 1/4"	SR+OT2032C	051114S
22G x 1"	SR+OT2225C	050818S
	SR+OT2225C6	111017SB
24G x ³ /4"	SR+OT2419C	051117S
	SR+OT2419C6	111013SB

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