

DECLARATION OF CONFORMITY

Manufacturer: Terumo Medical Products(Hangzhou) Co.,Ltd,
M4-9-5 Hangzhou Economic & Technological Development Zone,
310018 Hangzhou, People's Republic of China

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

Product Name: Winged Infusion Set

Model Number: See attachment

UMDNS Code: 17825

Classification (MDD, Annex IX): IIa, rule 7

Conformity Assessment Route: Annex II, excluding 4

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Standard Applied: All applicable harmonized standard

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

Identification number: CE0123

(EC) Certificate: G1 037584 0027 Rev.01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: Nov. 23,2004

Place of Issue: Hangzhou

Date: 2019.10.10

Signature: Zhang Yan.

Name: Zhang Yan

Position: General Manager

ATTACHMENT:

Common Name: Winged Infusion Set			
Brand Name	Model number		
Surflo Winged Infusion Set with Protector	SV*S18NL30	SV*S18BL30	SV*S21NL30B
	SV*S19NL30	SV*S19BL30	SV*S22NL30B
	SV*S21NL30	SV*S21BL30	SV*S23NL30B
	SV*S22NL30	SV*S22BL30	
	SV*S23NL30	SV*S23BL30	
	SV*S25NL30	SV*S25BL30	
	SV*S18NL18	SV*S21BL18	
	SV*S19NL18	SV*S22BL18	
	SV*S21NL18	SV*S23BL18	
	SV*S22NL18	SV*S25BL18	
	SV*S23NL18		
	SV*S25NL18		
	SV*S18NL09		
	SV*S19NL09		
	SV*S21NL09		
	SV*S22NL09		
	SV*S23NL09		
	SV*S25NL09		
Surshield Safety Winged Infusion Set	SV*S19BL		
	SV*S21BL		
	SV*S23BL		
	SV*S25BL		
	SV*S19BLS		
	SV*S21BLS		
	SV*S23BLS		
	SV*S25BLS	SV*S25BL23B	
Surflo Winged Infusion Set with Needle Protection	SV*S25BLSE		
Surflo Winged Infusion Set	SV*19BL18	SV*19NL30	SV*19NL30B
	SV*21BL18	SV*21NL30	SV*21NL30B
	SV*22BL18	SV*22NL30	SV*22NL30B
	SV*23BL18	SV*23NL30	SV*23NL30B
	SV*25BL18	SV*25NL30	SV*25NL30B