

EU DECLARATION OF CONFORMITY

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

with Single Registration Number of (SRN): CN-MF-000001640

being the manufacturer of:

Winged Infusion Set

Intended purpose: This product together with disposable infusion apparatus is used for intravenous injection and it is also provided with safety unit to prevent mal-puncture. (There is no safety unit for Surflo Winged Infusion Set)

Basic UDI-DI: Winged Infusion Set: 69276755SVKN

Winged Infusion Set with Protector: 69276755SVSAM

Note: Winged Infusion Set's Brand Name Included: Surflo Winged Infusion Set

Winged Infusion Set with Protector's Brand Name Included: Surflo Winged Infusion Set with Protector, Surshield Safety Winged Infusion Set, Surflo Winged Infusion Set with Needle Protection

Related product codes: See Appendix (full list of active codes)

declare that the above product of Class IIa is in conformity with applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the "Conformity assessment based on a quality management system and on assessment of technical documentation" set out in Annex IX, and by certification of Annex IX.3 (EU quality management system certificate number: G10 037584 0029), under the supervision of [TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany] as Notified Body authorized by the Germany Competent Authority and carrying the Notified Body NO.[0123].

Authorised Representative: TERUMO EUROPE N.V.,

Interleuvenlaan 40,3001 LEUVEN, BELGIUM

with Single Registration Number of (SRN): BE-AR-000001433

This EU declaration of conformity is issued under our sole responsibility.

Hangzhou 2024.05.10

(Place, Date of Issue)

Hui Weng

Hui Weng

Person responsible for regulatory compliance

[Terumo Medical Products(Hangzhou) Co.,Ltd]

Appendix A-Related product codes

Appendix:

Common Name: Winged Infusion Set			
Brand Name	Model number		
Surflo Winged Infusion Set with Protector	SV*S18NL30	SV*S21BL18	SV*S18NL09
	SV*S19NL30	SV*S22BL18	SV*S19NL09
	SV*S21NL30	SV*S23BL18	SV*S21NL09
	SV*S22NL30	SV*S25BL18	SV*S22NL09
	SV*S23NL30	SV*S18NL18	SV*S23NL09
	SV*S25NL30	SV*S19NL18	SV*S25NL09
	SV*S21NL18		
	SV*S22NL18		
	SV*S23NL18		
	SV*S25NL18		
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*18NL30
	SV*21BL18	SV*21NL30	SV*19NLK
	SV*22BL18	SV*22NL30	SV*21NLK
	SV*23BL18	SV*23NL30	SV*22NLK
	SV*25BL18	SV*25NL30	SV*23NLK
	SV*23NL30B	SV*25NL30B	SV*25NLK
	SV*27ELJ	SV*25NLSA02	
	SV*18BLK	SV*19BLK	SV*21BLK
	SV*22BLK	SV*23BLK	SV*25BLK
	SV*19BLS	SV*21BLS	SV*23BLS
	SV*25BLS	SV*25EL	SV*27EL
	SV19BLSF	SV21BLSF	SV23BLSF
	SV25BLSF	SV25ELF	SV27ELF