

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 Rev.00), 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

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

Hangzhou, 2023.05.11

(Place, Date of Issue)



Yuqing Lin

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	