



DECLARATION OF CONFORMITY

Manufacturer's name Nipro Corporation

Manufacturer's address 3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, JAPAN

European Representative's name NIPRO MEDICAL EUROPE

European Representative's address Blokhuisstraat 42, 2800 Mechelen, BELGIUM

Name of device(s) (Classification)  
Packed Needles (IIa), PSV Sets(IIa), AVF Needles(IIa), Blood Lines(IIa), I.V. Catheters(IIa),  
Syringes with Needles(IIa), Blood Collection Sets (IIa)

Description of Device(s) See attachments

We hereby ensure and declare that the device(s) concerned meet(s) the provisions of the MDD 93/42/EEC.

This declaration is supported by:

EC quality system approval statement (Annex II excluding 4) No. G1 043398 0279 Rev. 01 issued by TUV SUD Product Service GmbH (ID No.0123), Ridlerstr. 65, D-80339 München, Germany on 31 October 2019.

In addition, manufacturer is exclusively responsible for this declaration of conformity.

Place Osaka, Japan

Kazuhiko Hirata (Signature)  
Manager  
Medical Regulatory Affairs Department,  
Quality Assurance & Regulatory  
Compliance Headquarters  
(Position)

Date 25 March, 2020

Attached: Attachment 1-7





SafeTouch AVF

Attachment 3-2

No.	Product	Wing color	Cannula back eye	Tube length	Mini clamp and connector color	Sterilization method
1	ST.AVF 14x1"HTC-15R	Violet	Have	150mm	Red	EOG
2	ST.AVF 14x1"HTC-30R	Violet	Have	300mm	Red	
3	ST.AVF 14x1"TC-15B	Violet	Not have	150mm	Blue	
4	ST.AVF 14x1"TC-30B	Violet	Not have	300mm	Blue	
5	ST.AVF 14x1"C-15B	Violet	Not have	150mm	Blue	
6	ST.AVF 14x1"C-30B	Violet	Not have	300mm	Blue	
7	ST.AVF 14x1"HC-30R	Violet	Have	300mm	Red	
8	ST.AVF 14x1"HC-15R	Violet	Have	150mm	Red	
9	ST.AVF 14x1"HC-30B	Violet	Have	300mm	Blue	
10	ST.AVF 14x1"HC-15B	Violet	Have	150mm	Blue	
11	ST.AVF 14x1"HC-30W	Violet	Have	300mm	White	
12	ST.AVF 14x1"HC-15W	Violet	Have	150mm	White	
13	ST.AVF 15x1"C-15B	Ivory	Not have	150mm	Blue	
14	ST.AVF 15x1"C-30B	Ivory	Not have	300mm	Blue	
15	ST.AVF 15x1"HC-15R	Violet	Have	150mm	Red	
16	ST.AVF 15x1"HC-30R	Violet	Have	300mm	Red	
17	ST.AVF 15x1"HC-15B	Violet	Have	150mm	Blue	
18	ST.AVF 15x1"HC-30B	Violet	Have	300mm	Blue	
19	ST.AVF 15x1"HC-15W	Violet	Have	150mm	White	
20	ST.AVF 15x1"HC-30W	Violet	Have	300mm	White	
21	ST.AVF 15x1"HTC-15R	Violet	Have	150mm	Red	
22	ST.AVF 15x1"HTC-30R	Violet	Have	300mm	Red	
23	ST.AVF 15x1"TC-15B	Violet	Not have	150mm	Blue	
24	ST.AVF 15x1"TC-30B	Violet	Not have	300mm	Blue	
25	ST.AVF 16x1"C-15B	Green	Not have	150mm	Blue	
26	ST.AVF 16x1"C-30B	Green	Not have	300mm	Blue	
27	ST.AVF 16x1"HC-15R	Green	Have	150mm	Red	
28	ST.AVF 16x1"HC-30R	Green	Have	300mm	Red	
29	ST.AVF 16x1"HC-15B	Green	Have	150mm	Blue	
30	ST.AVF 16x1"HC-30B	Green	Have	300mm	Blue	
31	ST.AVF 16x1"HC-15W	Green	Have	150mm	White	
32	ST.AVF 16x1"HC-30W	Green	Have	300mm	White	
33	ST.AVF 16x1"HTC-15R	Green	Have	150mm	Red	
34	ST.AVF 16x1"HTC-30R	Green	Have	300mm	Red	
35	ST.AVF 16x1"TC-15B	Green	Not have	150mm	Blue	
36	ST.AVF 16x1"TC-30B	Green	Not have	300mm	Blue	
37	ST.AVF 17x1"C-15B	Orange	Not have	150mm	Blue	
38	ST.AVF 17x1"C-30B	Orange	Not have	300mm	Blue	
39	ST.AVF 17x1"HC-30R	Orange	Have	300mm	Red	
40	ST.AVF 17x1"HC-15R	Orange	Have	150mm	Red	
41	ST.AVF 17x1"HC-30B	Orange	Have	300mm	Blue	
42	ST.AVF 17x1"HC-15B	Orange	Have	150mm	Blue	
43	ST.AVF 17x1"HC-30W	Orange	Have	300mm	White	
44	ST.AVF 17x1"HC-15W	Orange	Have	150mm	White	
45	ST.AVF 17x1"HTC-15R	Orange	Have	150mm	Red	
46	ST.AVF 17x1"HTC-30R	Orange	Have	300mm	Red	
47	ST.AVF 17x1"TC-15B	Orange	Not have	150mm	Blue	
48	ST.AVF 17x1"TC-30B	Orange	Not have	300mm	Blue	



**AVF set Gamma**

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 2.10mm	Violet	4/5" 20mm	with eye	Fixed	300mm	Transparent	White	Gamma
15G 1.80mm	Ivory	1" 25mm	without eye	Turn	150 mm	Red	Red	
16G 1.60mm	Green	1 1/4" 32mm				Blue	Blue	
17G 1.40mm	Orange							

**Single needle Gamma**

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 2.10mm	Violet	4/5" 20mm	with eye	Fixed	125 mm	Red	Transparent	Gamma
15G 1.80mm	Ivory	1" 25mm	without eye	Turn	275mm	Blue		
16G 1.60mm	Green	1 1/4" 32mm						
17G 1.40mm	Orange							

**SafeTouch AVF Gamma**

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 2.10mm	Violet	4/5" 20mm	with eye	Fixed	300mm	White	White	Gamma
15G 1.80mm	Ivory	1" 25mm	without eye	Turn	150 mm	Red	Red	
16G 1.60mm	Green	1 1/4" 32mm				Blue	Blue	
17G 1.40mm	Orange							

**BioHole Needle (Gamma)**

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 2.0mm	Violet	4/5" 20mm	with eye	Fixed	300mm	Transparent	White	Gamma
15G 1.8mm	Ivory	1" 25mm	without eye	Turn	150 mm			
16G 1.6mm	Light-green	1 1/4" 32mm						
17G 1.5mm	Orange							

**BioHole needle (EtO)**

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 2.0mm	Violet	4/5" 20mm	with side hole without eye	Fixed	150mm	White	Natural	EtO
15G 1.8mm	Ivory	1" 25mm		Turn	300mm		Red	
16G 1.6mm	Green	1 1/4" 32mm			400mm		Blue	
17G 1.5mm	Orange							



Single needle Dull AVF

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 2.0mm	Violet	4/5" 20mm	with eye	Fixed	125 mm	Red	White	Gamma
15G 1.8mm	Ivory	1" 25mm	without eye	Turn	275mm	Blue		
16G 1.6mm	Light-green	1 1/4" 32mm						
17G 1.5mm	Orange							



**SafeTouch TULIP EtO**

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 15G 16G 17G	Violet Ivory Green Orange	1" 25mm	with eye without eye	Fixed Turn	12 inch 300mm	White	Natural	EtO

**SafeTouch TULIP Gamma**

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 15G 16G 17G	Violet Ivory Green Orange	1" 25mm	with eye without eye	Fixed Turn	12 inch 300mm	White Red Blue	Natural Red Blue	Gamma

**Dull AVF with Scab Remover**

Needle gauge	Wing / Hub color	Needle length	Tubing length	Color of mini clamp	Color of Luer connector	Sterilization method
14G 15G 16G 17G	Violet Ivory Light-green Orange	1 inch 1 1/4 inch 4/5"	12 inch 300mm 6 inch 150 mm	Red Blue	Red Blue	Gamma

**Dull AVF Single Needle Set with Scab Remover**

Needle gauge	Wing / Hub color	Needle length	Tubing length	Color of mini clamp	Color of Luer connector	Sterilization method
14G 15G 16G 17G	Violet Yellow Green Red	1 inch 1 1/4 inch 4/5"	11 inch 275mm 5 inch 125 mm	Red Blue	Red Blue	Gamma



**BioHole SafeTouch Tulip AVF Needle (Gamma)**

Needle gauge	Wing / Hub color	Needle length	Needle type	Wing type	Tubing length	Color of mini clamp	Color of luer connector	Sterilization method
14G 2.10 mm. 15G 1.80 mm. 16G 1.60 mm. 17G 1.40 mm.	Violet Ivory Green Orange	4/5" 20mm 1" 25mm 1 1/4" 32mm	with eye without eye	Fixed Turn	150mm 300mm	Transparent	White	Gamma