



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

NAGASAWA Yoshiki (Signature)
General Manager
Medical Regulatory Affairs Department,
Quality Assurance & Regulatory
Compliance Headquarters
(Position)

Date 10 March 2021

Attached: Attachment 1-7



Safe Touch PSV

Ref No.	Model
PSV SF 19 ET	19GX3/4" EL LUER CAP 300MM.
PSV SF 21 ET	21GX3/4" EL LUER CAP 300MM.
PSV SF 22 ET	22GX3/4" EL LUER CAP 300MM.
PSV SF 23 ET	23GX3/4" EL LUER CAP 300MM.
PSV SF 25 ET	25GX3/4" EL LUER CAP 300MM.

Safe Touch PSV Low priming volume

Product	Diameter	Cannula bevel		Spec. Color	Tube length		Tube's material		Tube Dia.	Connector	Cap	Sterilization method
		LS	LR		300mm	350mm	PVC	DEHP free				
ST PSV 25G x 3/4"	25G (0.5mm)	✓	-	ISO	-	✓	✓	✓	0.05mm	Hard	EL	EOG



Safe Touch AVF

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	3/5" 15mm						

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	Fixed	150mm	White	Natural	EtO
15G 1.8mm	Ivory	1" 25mm	without eye	Turn	300mm		Red	
16G 1.6mm	Green	1 1/4" 32mm			400mm		Blue	
17G 1.5mm	Orange							



Attachment 3-4

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	Violet	1" 25mm	with eye	Fixed	12 inch 300mm	White	Natural	EtO
15G	Ivory		without eye	Turn				
16G	Green							
17G	Orange							

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	Violet	1" 25mm	with eye	Fixed	12 inch 300mm	White	Natural	Gamma
15G	Ivory		without eye	Turn		Red	Red	
16G	Green					Blue	Blue	
17G	Orange							

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	Violet	1 inch	12 inch 300mm	Red	Red	Gamma
15G	Ivory	1 1/4 inch	6 inch 150 mm	Blue	Blue	
16G	Light-green	4/5"				
17G	Orange					

Dull AVF Single Needle Set with Scab Remover

Needle gauge	Wing / Hub color	Needle length	Wing Type	Tubing length	Sterilization method
14G	Violet	4/5" (20mm.)	Fixed	125mm.	Gamma
15G	Ivory	1" (25mm.)	Turn	275mm.	
16G	Light-green				
17G	Orange				



Attachment 3-6

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	Violet	1" 25mm	with back-eye	Fixed	150mm	Red	Red	Gamma
15G	Ivory	1 1/4" 32mm	without back-eye	Turn	300mm	Blue	Blue	
16G	Green							
17G	Orange							



Description of Blood Lines (IIa)

No.	Model	Sterilization Method
1	A041-V608	EOG
2	A042-V613	
3	A044-V610	
4	A045-V612	
5	A047-V610	
6	V644	
7	A112-V682	
8	A114-V684	
9	A121-V691	
10	A133-V702	
11	A134-V721	
12	A135-V704	
13	A146-V715	
14	A147-V716	
15	A162-V730	
16	A163-V731	
17	A164-V732	
18	A165-V733	
19	A170-V739	
20	A176-V684	
21	A179-V747	
22	A181-V749	
23	A183-V751	
24	A186-V754	
25	A187-V755	
26	A188-V756	
27	A189-V757	
28	A198-V766	
29	A199-V767	
30	A200-V768	
31	A250-V775	
32	A251-V776	
33	V782	
34	A272-V783	
35	A289-V800	
36	A316-V814	
37	A324-V822	
38	A326-V824	
39	A342-V840	
40	A343-V715	
41	A344-V716	
42	A345-V717	
43	A415-V898	
44	A030/V613	
45	A071/V648	
46	A147-V715	
47	A150/V696	
48	A158/V726	
49	NS-2060-1	
50	NS-2060-2	
51	NS-2060-4	
52	NS-2060-4L	
53	NS-2060-5	

No.	Model	Sterilization Method
54	NS-2060-5L	EOG
55	NS-2060-6	
56	NS-2060-7	
57	NS-2060-8	
58	NS-2060-14	
59	NS-2060-15	
60	NS-2060-18	
61	NS-2060-18SUB	
62	NS-2060-19	
63	A004/V612	
64	A017/V604	
65	A108/V677	
66	A109/V678	
67	A108CD/V677CD	
68	A109CD/V678CD	



Attachment 4-2

No.	Model	Sterilization Method
1	A165R-V733R	GAMMA
2	A189R-V757R	
3	A196R-V764R	
4	A197R-V765R	
5	A277R-V788R	
6	A290R-V801R	
7	A295R-V806R	
8	A297R-V808R	
9	A316R-V814R	
10	A317R-V815R	
11	A320R-V818R	
12	A329R-V827R	
13	A414R-V897R	
14	B0004R	
15	B0005R	
16	A009(M2)R/V603(M2)R	
17	A010(H3)R/V604(H3)R	
18	A015(H1)R/V609(H1)R	
19	A015(H5)R/V609(H5)R	
20	A015(H6)R/V609(H6)R	
21	A015(H6)R/V609(H8)R	
22	A015(H6)R/V609(H9)R	
23	A073R/V650R(G3D)	
24	A123R/V693R	
25	A131R/V700R	
26	A152R/V719R	
27	A158R/V726R	
28	A189R/V757R	
29	A260R/V778R	
30	A260R(MU)/V778R(MU)	
31	A290R-V801R	
32	V375R/V875R	
33	A439E-V919R	
34	A434R-V914R	



Attachment 4-3

No.	Model	Sterilization Method
1	A197TR-V765TR	GAMMA
2	A205TR-V773TR	
3	A347TR-V719TR	
4	A360TR-V846TR	
5	A363R-V849R	
6	A364R-V850R	
7	A365R-V851R	
8	A366R-V852R	
9	A367R-V853R	
10	A367TR-V853TR	
11	A368R-V854R	
12	A368TR-V854TR	
13	A369R-V855R	
14	A370R-V856R	
15	A370TR-V856TR	
16	A372R-V858R	
17	A373R-V859R	
18	A438R-V918R	
19	B0002TR	
20	B0003TR	
21	B0004TR	
22	B0006TR	
23	B0007TR	
24	A144DR/V713DR	
25	A363R-V849R	
26	A364R-V850R	
27	A365R-V851R	
28	A372R-V858R	
29	A373R-V859R	
30	A426DR/V908DR	
31	NS-2060-15DR	
32	A446R-V926R	
33	A447R-V927R	



Attachment 5-1

Description of I.V. Catheters(IIa)

No.	Size	Sterilization Method
1	16G x 2"	EOG
2	18G x 2"	
3	18G x 1 1/4"	
4	20G x 2"	
5	20G x 1 1/4"	
6	22G x 1"	
7	22G x 1 1/4"	
8	24G x 3/4"	
9	24G x 1"	



Description of Safe Touch Catheters (IIa)

1st Batch Information

Grade/ Size : Safe Touch Cath 20G x 1 1/4"

Lot No. : 10L24

No.	Size	Sterilization Method
1	14G x 2"	EOG
2	16G x 2"	
3	18G x 2"	
4	18G x 1 1/4"	
5	20G x 2"	
6	20G x 1 1/4"	
7	20G x 1"	
8	22G x 1"	
9	22G x 1 1/4"	
10	24G x 3/4"	
11	24G x 1"	

Description of Syringes with Needles(IIa)

Size	With Needle		Sterilization Method
	Luer slip tip	Luer lock tip	
1 ml	✓	✓	EOG
2 ml	✓	✓	
3 ml	✓	✓	
5 ml	✓	✓	
10 ml	✓	✓	
20 ml	No produce	No produce	

Remark : "✓" means already produced.



Description of Blood Collection Sets (IIa)

Safe Touch Blood Collection Sets

Ref No.	Model
BCS SF 21-19 ET	21GX3/4" LUER ADAPTER 190MM.
BCS SF 21-30 ET	21GX3/4" LUER ADAPTER 300MM.
BCS SF 22-19 ET	22GX3/4" LUER ADAPTER 190MM.
BCS SF 22-30 ET	22GX3/4" LUER ADAPTER 300MM.
BCS SF 23-19 ET	23GX3/4" LUER ADAPTER 190MM.