

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 Europe N.V.

European Representative's address Weihoek 3 H, 1930 Zaventem, 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

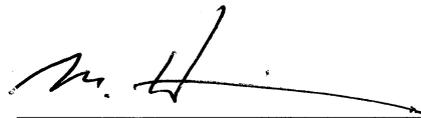
We hereby ensure and declare that the device(s) concerned meet(s) the provisions of the MDD 93/42/EEC.

This declaration is supported by:

EC quality system approval statement (Annex II excluding 4) No. G1 17 08 43398 273 issued by TUV SUD Product Service GmbH (ID No.0123), Ridlerstr. 65, D-80339 München, Germany on 7 September 2017.

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

Place Osaka, Japan



Minoru Doimoto (Signature)
Deputy General Manager
Quality Assurance & Regulatory
Compliance Division
(Position)

Date 14 October 2017

Attached: Attachment 1-7

Description of PSV Sets (IIa)

PSV set

Type	Tube length 300mm	Needle Length (inch)		Color of wing		Type of connector		Tube's material		Sterilization method
		3/4"	5/8"	Nipro	ISO	Soft	Hard	PVC	DEHP free	
18G	✓	✓	-	✓	✓	✓	✓	✓	✓	EOG
19G	✓	✓	-	✓	✓	✓	✓	✓	✓	
20G	✓	✓	-	✓	✓	✓	✓	✓	✓	
21G	✓	✓	✓	✓	✓	✓	✓	✓	✓	
22G	✓	✓	✓	✓	✓	✓	✓	✓	✓	
23G	✓	✓	✓	✓	✓	✓	✓	✓	✓	
24G	✓	✓	-	✓	✓	✓	✓	✓	✓	
25G	✓	✓	✓	✓	✓	✓	✓	✓	✓	
26G	-	-	-	✓	-	-	-	-	-	
27G	✓	✓	-	✓	✓	✓	✓	✓	✓	

Safe Touch PSV

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 19G x 3/4"	19G (1.1mm)	✓	-	ISO	✓	-	✓	✓	1.35mm	Hard	EL	EOG
ST PSV 21G x 3/4"	21G (0.8mm)	✓	-	ISO	✓	-	✓	✓	1.35mm	Hard	EL	
ST PSV 22G x 3/4"	22G (0.7mm)	✓	-	ISO	✓	-	✓	✓	1.35mm	Hard	EL	
ST PSV 23G x 3/4"	23G (0.6mm)	✓	-	ISO	✓	-	✓	✓	1.35mm	Hard	EL	
ST PSV 25G x 3/4"	25G (0.5mm)	✓	-	ISO	✓	-	✓	✓	1.35mm	Hard	EL	

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

SafeTouch AVF

No.	Product	Wing color	Cannula back eye	Tube length	Mini clamp and connector color	Sterilization method
1	ST.AVF 14x1"HC-15R	Violet	Have	150mm	Red	EOG
2	ST.AVF 14x1"HC-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"HC-15R	Violet	Have	150mm	Red	
22	ST.AVF 15x1"HC-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"HC-15R	Green	Have	150mm	Red	
34	ST.AVF 16x1"HC-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"HC-15R	Orange	Have	150mm	Red	
46	ST.AVF 17x1"HC-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 2.0mm	Violet	4/5" 20mm	with eye	Fixed	300mm	Transparent	White	Gamma
15G 1.8mm	Ivory	1" 25mm	without eye	Turn	150 mm	Red	Red	Gamma
16G 1.6mm	Light-green	1 1/4" 32mm				Blue	Blue	
17G 1.5mm	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 2.0mm	Violet	4/5" 20mm	with eye	Fixed	125 mm	Red	Transparent	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							

Safe Touch 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 2.0mm	Violet	4/5" 20mm	with eye	Fixed	300mm	White	White	Gamma
15G 1.8mm	Ivory	1" 25mm	without eye	Turn	150 mm	Red	Red	
16G 1.6mm	Light-green	1 1/4" 32mm				Blue	Blue	
17G 1.5mm	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							

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

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	Blue	1 1/4" 32mm	without back-eye	Turn	300mm	Blue	Blue	
16G	Green							
17G	Orange							

Description of Blood Lines (IIa)

No.	Model	Sterilization Method	No.	Model	Sterilization Method
1	A021 / V613	EOG	55	A346 / V718	EOG
2	A041 / V608		56	A415 / V898	
3	A042 / V613		57	A030 / V613	
4	A044 / V610		58	A071 / V648	
5	A045 / V612		59	A071(8.0mm.+TP)/V648	
6	A047 / V610		60	A071(8.0mm)/V648	
7	A068 / V644		61	A126 / V696	
8	A068 / V728		62	A127 / V697	
9	A069 / V610		63	A142 / V711	
10	A072 / V649		64	A143 / V712	
11	A089 / V664		65	A147 / V715	
12	A112 / V682		66	A147 / V716	
13	A114 / V684		67	A149 / V691	
14	A121 / V691		68	A150 / V696	
15	A133 / V702		69	A150 / V697	
16	A134 / V721		70	A156 / V724	
17	A135/V704 and A147/V716		71	A158 / V726	
18	A146 / V715		72	NS-2060-1	
19	A162 / V730		73	NS-2060-2	
20	A163 / V731		74	NS-2060-4	
21	A164 / V732		75	NS-2060-4L	
22	A165 / V733		76	NS-2060-5	
23	A170 / V739		77	NS-2060-5L	
24	A176 / V684		78	NS-2060-6	
25	A179 / V747		79	NS-2060-7	
26	A181 / V749		80	NS-2060-8	
27	A183 / V751		81	NS-2060-14	
28	A186 / V754		82	NS-2060-15	
29	A187 / V755		83	NS-2060-18	
30	A188 / V756		84	NS-2060-18 SUB	
31	A189 / V757		85	NS-2060-BJC	
32	A195 / V763		86	A004 / V612	
33	A198 / V766		87	A017 / V604	
34	A199 / V767		88	A105(P)CDM / V671CDM	
35	A200 / V768		89	A108 / V677	
36	A250 / V775		90	A109 / V678	
37	A251 / V776		91	A108CD / V677CD	
38	A271 / V782		92	A109CD / V678CD	
39	A272 / V783		93	A157 / V725	
40	A275 / V786		94	A123 / V693	
41	A277 / V788		95	A131 / V700	
42	A280 / V791		96	A130(S) / V699(B)	
43	A283 / V794		97	A169 / V738	
44	A289 / V800		98	A334 / V832	
45	B0001		99	A336 / V834	
46	B0002		100	A192 / V760	
47	A316 / V814		101	A065(J) / V643(J)	
48	A319 / V817		102	A168 / V737	
49	A324 / V822		103	A268 / V778	
50	A326 / V824		104	A335 / V833	
51	A342 / V840		105	A337 / V835	
52	A343 / V715				
53	A344 / V716				
54	A345 / V717				

Attachment 4-2

No.	Model	Sterilization Method	No.	Model	Sterilization Method
1	A003(M1)R/V612(M1)R	GAMMA	56	A371R / V857R	GAMMA
2	A004(M1)R		57	A394R / V880R	
3	A007R		58	A395R / V881R	
4	A009(M2)R/V603(M2)R		59	A396R / V882R	
5	A025(M4)R		60	A405R / V889R	
6	A025(M4)R/V612(M1)R		61	A406R / V890R	
7	A025(M5)R		62	A413R / V896R	
8	V602R		63	A414R/V897R	
9	A042R / V613R		64	A422R / V905R	
10	A044R / V610R		65	B0001R	
11	A068R / V728R		66	B0002R	
12	A146R / V715R		67	B0004R	
13	A164R / V732R		68	B0005R	
14	A165R / V733R		69	A009(M2)R/V603(M2)R	
15	A172R / V741R		70	A015(H1)R/V609(H1)R	
16	A176R / V684R		71	A015(H5)R/V609(H5)R	
17	A183R / V751R		72	A015(H6)R/V609(H6)R	
18	A184R / V752R		73	A015(H6)R/V609(H8)R	
19	A186R / V752R		74	A015(H6)R/V609(H9)R	
20	A188R / V756R		75	A034R / V618R	
21	A189R / V757R		76	A058R / V634R	
22	A195R / V763R		77	A073R / V650R(G3D)	
23	A196R / V764R		78	A105R / V671R	
24	A197R / V765R		79	A105R / V671R(D)	
25	A198R / V766R		80	A131R / V700R	
26	A252R / V777R		81	A152R/V719R	
27	A269R / V780R		82	A158R / V726R	
28	A270R / V781R		83	A175R / V744R	
29	A271R / V782R		84	A189R / V757R	
30	A275R / V786R		85	A254R(M) / V779R(M)	
31	A277R / V788R		86	A260R(M) / V778R	
32	A280R / V791R		87	A260R (MAU) / V778R (MAU)	
33	A287R / V798R		88	A416R/V899R	
34	A288R / V798R		89	A417R/V900R	
35	A290R / V801R		90	A418R/V901R	
36	A291R / V802R		91	A419R/V902R	
37	A292R / V803R		92	A420R/V903R	
38	A294R / V805R		93	A421R/V604R	
39	A295R / V806R				
40	A296R / V807R				
41	A297R / V808R				
42	A316R / V814R				
43	A317R / V815R				
44	A318R / V816R				
45	A319R / V817R				
46	A320R / V818R				
47	A321R / V819R				
48	A322R / V820R				
49	A323R / V821R				
50	A329R / V827R				
51	A341R / V839R				
52	A355R / V842R				
53	A356R / V843R				
54	A357R / V844R				
55	A359R / V845R				

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

Product	Diameter	Cannula bevel		Spec. Color	Tube length		Tube's Material		Tube Diameter	Connector	Cap	Sterilization Method
		LS	LR		190 mm.	300 mm.	PVC	DEHP Free				
ST PSV 21G x 3/4"	21G (0.8 mm.)	✓	—	ISO	✓	✓	✓	—	1.35 mm.	Hard	Luer Adapter	EOG
ST PSV 22G x 3/4"	22G (0.7 mm.)	✓	—	ISO	✓	✓	✓	—	1.35 mm.	Hard	Luer Adapter	
ST PSV 23G x 3/4"	23G (0.6 mm.)	✓	—	ISO	✓	✓	✓	—	1.35 mm.	Hard	Luer Adapter	