



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

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

Date 25 January 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 |



SafeTouch 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 | | | | | | | |



Single needle Dull AVF

Attachment 3-4

| 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 (Ila)

| 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 | A147-V716 | |
| 48 | A150/V696 | |
| 49 | A158/V726 | |
| 50 | NS-2060-1 | |
| 51 | NS-2060 2 | |
| 52 | NS-2060-4 | |
| 53 | NS-2060-4L | |
| 54 | NS-2060-5 | |

| No. | Model | Sterilization Method |
|-----|---------------|----------------------|
| 55 | NS-2060-5L | EOG |
| 56 | NS-2060-6 | |
| 57 | NS-2060-7 | |
| 58 | NS-2060-8 | |
| 59 | NS-2060-14 | |
| 60 | NS-2060-15 | |
| 61 | NS-2060-18 | |
| 62 | NS-2060-18SUB | |
| 63 | NS-2060-19 | |
| 64 | A004/V612 | |
| 65 | A017/V604 | |
| 66 | A108/V677 | |
| 67 | A109/V678 | |
| 68 | A108CD/V677CD | |
| 69 | A109CD/V678CD | |
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| 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 | |



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. |