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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

NIPRO CORPORATION
3-26, Senriokashinmachi, Settsu
Osaka
566-8510, JAPAN

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
043398	Confirmation number of non-binding quote	medical_devices@tuvsud.com		2024-12-30	1 of 12

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 043398 0320 Rev. 01

Reference: JN1465565 | JN1752570 | JN1761926 | JN66460377 | JN65229210 | JN71024494 | JN71024498 | JN200350003356

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: JP-MF-000026759

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see **www.tuvsud.com/ps-cert?q=cert:CL 043398 0320**

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-12-30

TÜV SÜD Product Service GmbH
Medical and Health Services

Shinichi Kawabata
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Fatlume Bahtiri
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **Single Patient Dialysis Machine** 49684200TDS1011NT 49684200TDS1012NV 49684200TDS1013NX 49684200TDS1014NZ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0283 Rev. 01; NB# 0123 (Single Patient Dialysis Machine)
Device 2 **SYNTHETIC HEMODIALYZER** 49684200TDA1011GM 4968420TDHE1011XW 4968420TDIN10113H	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialyzers)
Device 3 **DIALYZER** 49684200TDA1011GM	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialyzers)
Device 4 **HEMODIALYZER** 49684200TDA1021GQ 49684200TDA1022GS	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		(Hemodialyzers)
Device 5 **AMBULATORY BALLOON INFUSER** 49684200TDA1061H4 49684200TDA1062H6 49684200TDA1063H8 49684200TDA1064HA	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Balloon Infusers)
Device 6 **ENDOTOXIN-RETENTIVE FILTER** 4968420TDA1051GZ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Endotoxin Filter)
Device 7 **IV CANNULA** 49684200TDA1071H7 4968420TDIN10213L 4968420TDIJ102128	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; (Intravenous Catheters)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	function ☐ Class III implantable custom-made-device		
Device 8 **STOPCOCK** **49684200TDA1081HA** **49684200TDA1082HC**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Stopcocks)
Device 9 **BUTTONEHOLE DEVICE** 49684200TDA1091HD	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Biohole Kit)
Device 10 **HEMODIALYSIS NEEDLE** 49684200TDA1101GP	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialysis Catheter)
Device 11 **SAFETY HEMODIALYSIS NEEDLE** 49684200TDA1102GR	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialysis Catheter)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
49684200TDA1103GT	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 12 **BLOOD COLLECTION NEEDLE** **49684200TDG1011JP**	☒ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0276 Rev. 01; NB# 0123 (Blood Collecting Needles)
Device 13 **LUER ADAPTER** 49684200TDG1021JS	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0276 Rev. 01; NB# 0123 (Luer Adapter)
Device 14 **DENTAL NEEDLE** 49684200TDG1031JV	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring	☒ N/A	☒ Certification as follows: G1 043398 0276 Rev. 01; NB# 0123 (Dental Needle)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	function ☐ Class III implantable custom-made-device		
Device 15 **NEEDLELESS TRANSFER DEVICE** 49684200TDG1051K3	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G2S 043398 0290 Rev. 01; NB# 0123 (Transfer Needles)
Device 16 **NEEDLE** 49684200TDG1061K6	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Packed Needles)
Device 17 **WINGED NEEDLE SET** 49684200TDT1021P9	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (PSV Sets)
Device 18 **SAFETY WINGED NEEDLE SET** 49684200TDT1022PB	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (PSV Sets)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
49684200TDG1041JY	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 19 **A.V. Fistula Needle** 49684200TDT1061PM 4968420TDIN10313P	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)
Device 20 **Dull Fistula** 49684200TDT1061PM	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)
Device 21 **Safety A.V. Fistula Needle** 49684200TDT1062PP	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	function ☐ Class III implantable custom-made-device		
Device 22 **Safety Dull Fistula** 49684200TDT1062PP	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)
Device 23 **BLOOD TUBING SET FOR HEMODIALYSIS** 49684200TDT1091PW	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Blood Lines)
Device 24 **IV CANNULA** 49684200TDT1071PQ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (I.V. Catheters)
Device 25 **SAFETY BLOOD COLLECTION SET** 49684200TDT1042PH	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Blood Collection Sets)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 26 **Rinsing root canal** 49684200TDT1101P8	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G2S 043398 0281 Rev. 02; NB# 0123 (Blunt Needle)
Device 27 **SYRINGE WITH NEEDLE** 4968420TDIN10423U 4968420TDIJ101227	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Syringes with Needles)
Device 28 **SAFETY NEEDLE** **49684200TDT1012P8**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Packed Needles)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	function ☐ Class III implantable custom-made-device		
Device 29 **SAFETY IV CANNULA** 49684200TDT1072PS	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (I.V. Catheters)
Device 30 **BLOOD COLLECTION SET** 49684200TDT1041PF	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Blood Collection Sets)
Device 31 **SAFETOUCH HUBER INFUSION SET** 49684200TDT1031PC	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Huber Needles / Huber Needle Sets)
Device 32 **SCAB REMOVER** 49684200TDT1063PR	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G2S 043398 0281 Rev. 02; NB# 0123 (Scab Remover)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 33 **SYRINGE** 4968420TDIJ101125 4968420TDIN10413S	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☒ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G2MS 043398 0280 Rev. 01; NB# 0123 (Syringes without Needles)

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified during application review)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Not applicable	☐ N/A	☐ N/A	☐ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-03-11	JN1465565 | JN1752570 | JN1761926 | JN66460377 | JN65229210 | JN71024494 | JN71024498	Initial issue
2024-12-30	JN200350003356	Addition of Basic UDI-DI to device 2, 7. 18 and 19 Addition of device 30, 31, 32 and 33

NIPRO

DECLARATION OF CONFORMITY

Manufacturer's name	Nipro Corporation
Manufacturer's address	3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, JAPAN
European Representive's name	NIPRO MEDICAL EUROPE
European Representive's address	Blokhuisstraat 42, 2800 Mechelen, BELGIUM
Name of device(s) (Classification)	PSV Sets(IIa)
Description of Device(s)	See attachment

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

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

Date 24 May 2022

Attached: Attachment

Effective

Attachment

Description of PSV Sets (IIa)

Reference No.	Model
4056310N	19Gx3/4" (1,1x19 mm); L: 30 cm; Luer Lock
4056337N	21Gx3/4" (0,8x19 mm); L : 30 cm; Luer Lock
4056345N	22Gx3/4" (0,7x19 mm); L : 30 cm; Luer Lock
4056353N	23Gx3/4" (0,65x19 mm); L : 30 cm; Luer Lock
4056361N	24Gx3/4" (0,55x19 mm); L : 30 cm; Luer Lock
4056370N	25Gx3/4" (0,5x19 mm); L : 30 cm; Luer Lock
4056388N	27Gx5/8" (0,4x16 mm); L: 30 cm; Luer Lock

Effective

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 043398 0279 Rev. 01

Manufacturer: **Nipro Corporation**
3-9-3, Honjo-Nishi, Kita-ku
Osaka 531-8510
JAPAN

Product Category(ies): **Packed Needles, PSV Sets, AVF Needles, Blood Lines, I.V. Catheters, Syringes with Needles, Blood Collection Sets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JNQ235037648**

Valid from: **2019-10-31**
Valid until: **2024-05-26**

Date, **2019-10-31**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 043398 0279 Rev. 01

Facility(ies):

Nipro Corporation
3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, JAPAN

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

TÜV®

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	NIPRO CORPORATION
Manufacturer address and contact details	3-26, Senriokashinmachi, Settsu, Osaka, 566-8510, Japan
Single Registration Number (SRN) (if available)	JP-MF-000026759

Authorised Representative name (if applicable)	Nipro Medical Europe
Authorised Representative address and contact details	Blokhuisstraat 42, 2800 Mechelen, Belgium
Single Registration Number (SRN) (if available)	BE-AR-000022416

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☒A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

M. Otani

OTANI Miho,
Manager, Medical Regulatory Affair Department,
Quality Assurance & Regulatory Compliance Headquarters
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NIPRO

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
VENOFIX SAFETY 1.1X19MM 19G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX SAFETY 0.8X19MM 21G 19CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX SAFETY 0.8X19MM 21G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX SAFETY 0.65X19MM 23G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX SAFETY 0.5X19MM 25G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX 1.1X19MM 19G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX 0.8X19MM 21G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX 0.7X19MM 22G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX 0.65X19MM 23G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX 0.55X19MM 24G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX 0.5X19MM 25G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	
VENOFIX 0.4X16MM 27G 30CM	G1 043398 0279 Rev.01	2024-05-26	Tüv Süd No. 0123	Tüv Süd No. 0123	End of 2028	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)