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

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

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
043398	See below	+81-3-3372-4821 Shinichi.Kawabata@tuvsud.com	050-3085-2174	2024-03-11	1 of 10

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 043398 0320 Rev. 00

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

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
11th March 2024

TÜV SÜD Product Service GmbH
Medical and Health Services

Shinichi Kawabata
Shinichi Kawabata (Mar 12, 2024 10:22 GMT+9)

Shinichi Kawabata
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Mar 11, 2024 14:18 GMT+1)

Michael Mauermeir
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	☐ 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) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialyzers)

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 I devices with measuring function ☐ Class III implantable custom-made-device		
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	☐ 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; (Intravenous Catheters)
Device 8 **STOPCOCK** 49684200TDA1081HA 49684200TDA1082HC	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Stopcocks)

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 I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
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 49684200TDA1103GT	☐ 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 12 **BLOOD COLLECTION NEEDLE** 49684200TDG1011JP	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 043398 0276 Rev. 01; NB# 0123 (Blood Collecting 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
	☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
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 function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0276 Rev. 01; NB# 0123 (Dental Needle)
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)	☒ N/A	☒ Certification as follows: G1 043398 0279 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		(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) ☐ 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 19 **A.V. Fistula Needle** 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 20 **Dull Fistula**	☐ Class III	☒ N/A	☒ Certification as follows:

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
49684200TDT1061PM	☐ 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		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 function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)
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 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 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) ☐ 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 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	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Syringes with 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
	☐ Class III implantable custom-made-device		
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 function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Packed Needles)
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)

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT 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 applcable	☒ 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