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 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
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 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

Facility(ies):

Nipro Corporation

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

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TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT



**Add value.
Inspire trust.**

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.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification Body for Medical Products
Ridlerstr. 65
80339 Munich
Germany

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Hotline: +49 89 50084-747





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

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)

Michael Mauormeir

[Michael Mauormeir \(Mar 11, 2024 14:18 GMT+1\)](#)

Michael Mauormeir
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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0283 Rev. 01; NB# 0123 (Single Patient Dialysis Machine)
Device 2 SYNTHETIC HEMODIALYZER 49684200TDA1011GM 4968420TDHE1011XW	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialyzers)
Device 3 DIALYZER 49684200TDA1011GM	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialyzers)
Device 4 HEMODIALYZER 49684200TDA1021GQ 49684200TDA1022GS	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 5 AMBULATORY BALLOON INFUSER 49684200TDA1061H4 49684200TDA1062H6 49684200TDA1063H8 49684200TDA1064HA	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Balloon Infusers)
Device 6 ENDOTOXIN-RETENTIVE FILTER 4968420TDA1051GZ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Endotoxin Filter)
Device 7 IV CANNULA 49684200TDA1071H7	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0275 Rev. 01; (Intravenous Catheters)
Device 8 STOPCOCK 49684200TDA1081HA 49684200TDA1082HC	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 9 BUTTONHOLE DEVICE 49684200TDA1091HD	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Biohole Kit)
Device 10 HEMODIALYSIS NEEDLE 49684200TDA1101GP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialysis Catheter)
Device 11 SAFETY HEMODIALYSIS NEEDLE 49684200TDA1102GR 49684200TDA1103GT	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0275 Rev. 01; NB# 0123 (Hemodialysis Catheter)
Device 12 BLOOD COLLECTION NEEDLE 49684200TDG1011JP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 13 LUER ADAPTER 49684200TDG1021JS	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0276 Rev. 01; NB# 0123 (Luer Adapter)
Device 14 DENTAL NEEDLE 49684200TDG1031JV	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0276 Rev. 01; NB# 0123 (Dental Needle)
Device 15 NEEDLELESS TRANSFER DEVICE 49684200TDG1051K3	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G2S 043398 0290 Rev. 01; NB# 0123 (Transfer Needles)
Device 16 NEEDLE 49684200TDG1061K6	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		(Packed Needles)
Device 17 WINGED NEEDLE SET 49684200TDT1021P9	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (PSV Sets)
Device 18 SAFETY WINGED NEEDLE SET 49684200TDT1022PB	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (PSV Sets)
Device 19 A.V. Fistula Needle 49684200TDT1061PM	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)
Device 20 Dull Fistula	<input type="checkbox"/> Class III	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)
Device 21 Safety A.V. Fistula Needle 49684200TDT1062PP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)
Device 22 Safety Dull Fistula 49684200TDT1062PP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (AVF Needles)
Device 23 BLOOD TUBING SET FOR HEMODIALYSIS 49684200TDT1091PW	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (I.V. Catheters)
Device 25 SAFETY BLOOD COLLECTION SET 49684200TDT1042PH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Blood Collection Sets)
Device 26 Rinsing root canal 49684200TDT1101P8	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G2S 043398 0281 Rev. 02; NB# 0123 (Blunt Needle)
Device 27 SYRINGE WITH NEEDLE 4968420TDIN10423U 4968420TDIJ101227	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class III implantable custom-made-device		
Device 28 SAFETY NEEDLE 49684200TDT1012P8	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 043398 0279 Rev. 01; NB# 0123 (Packed Needles)
Device 29 SAFETY IV CANNULA 49684200TDT1072PS	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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 applicable	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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