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

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Your reference/letter of	Our reference/name	Tel. extension/Email	Date	Page
	TPS3023_AR	keyur.baruwala@tuvsud.com	2024-05-26	1 of 10

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 041938 0010 Rev. 00**

Reference: TPS3023_AR

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: IN-MF-000003380

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.

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)
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- 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 041938 0010 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-18

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'Keyur Baruwala'.

Keyur Baruwala
Project Handler (PH)

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'Claus Matthias Mumme'.

Claus Matthias Mumme
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 IV Cannula / Catheter with/without Safety feature Basic UDI-DI: 890209510001CY	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 2 Infusion Sets Basic UDI-DI: 890209514001DU	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 3 Burette Infusion sets Basic UDI-DI: 890209514500EK	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 4 Flow Regulators Basic UDI-DI: 890209513100DQ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 5 Extension line Basic UDI-DI: 890209513180EG	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 6 CVP Manometers Basic UDI-DI: 890209513350EH	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 7 Stop cocks with/without extension line Basic UDI-DI: 890209513001DM	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 8 Needle free connectors with/without extension line Basic UDI-DI: 890209513057EG	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 9 Scalp Vein (Winged Infusion Set) with/without safety feature Basic UDI-DI: 890209513510EF	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 10 Manifolds with/without extension line Basic UDI-DI: 890209513710ER	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 11	☒ Class IIa	☒ 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
Transfusion Pump Set Basic UDI-DI: 890209570150FL			Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 12 Blood collection set with/without safety features Basic UDI-DI: 890209588290J8	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 13 Transfusion Sets (BT Set) Basic UDI-DI: 890209570090FT	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 14 Closed Wound Suction Unit Basic UDI-DI: 890209590050G5	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 15 Yankaur Suction Set (Suction tube and/or Handle) Basic UDI-DI: 890209590140G7	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 16 Thoracic Drainage Catheters with/without Trocar Basic UDI-DI: 890209590080GE	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 17 Redon Drainage Tubes Basic UDI-DI: 890209590060G8	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 18 Abdominal Drainage Set Basic UDI-DI: 890209590110FW	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 19 Under Water Sealed Drainage System Basic UDI-DI: 890209590120FZ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 20 Female catheters Basic UDI-DI: 890209530060E6	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 21 Nelaton catheters Basic UDI-DI: 890209530010DP	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 22 Foley Balloon Catheter	☒ Class IIa	☒ 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
Basic UDI-DI: 890209530303E9			Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 23 Irrigation Set Basic UDI-DI: 890209530520EK	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 24 Nasogastric Feeding tubes with/without guidewires (Single & Dual port)/Levin's Tube Basic UDI-DI: 890209540301EG	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 25 Ryle's Tubes Basic UDI-DI: 890209540001DZ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 26 Feeding Bags Basic UDI-DI: 890209540600EV	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 27 Mucus Extractor with/without bacterial Filter Basic UDI-DI: 890209540350EV	☒ Class IIa I	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 28 Suction Catheter Basic UDI-DI: 890209520010DC	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 29 Nasal Oxygen Catheter/ Cannula Basic UDI-DI: 890209520020DF	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 30 Oxygen Catheters Basic UDI-DI: 890209520060DT	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 31 Endotracheal Tube with Cuff / Without cuffed / Reinforced Basic UDI-DI: 890209520150DV	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 32 Catheter Mount Basic UDI-DI: 890209520180E6	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; 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
Device 33 Oxygen Mask Basic UDI-DI: 890209520115DT	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 34 Nebulizer Mask Basic UDI-DI: 890209520111DK	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 35 Venturi Mask Basic UDI-DI: 890209520120DL	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 36 Blood Line Set Basic UDI-DI: 890209570155FW	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 37 AV Fistula Needle with/without safety features Basic UDI-DI: 890209590030FX	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 38 Peritoneal Dialysis Catheter Kit Basic UDI-DI: 890209590350GL	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 39 Luer caps Basic UDI-DI: 890209513353EP	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 40 Stomach Tubes Basic UDI-DI: 890209540480FB	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 41 Guedel Airways Basic UDI-DI: 890209520050DQ	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 42 Peritoneal Dialysis Transfusion Set Basic UDI-DI: 890209590360GP	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 43 Umbilical Cord Clamp Basic UDI-DI: 890209590220G6	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 44	☒ Class Is	☒ 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
Urine Collection Bags with/without volume meter Basic UDI-DI: 890209530101DT			Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 45 Trans Urethral Resection Set (TUR Set) Basic UDI-DI: 890209530300E3	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 46 Sterile Bottle caps Basic UDI-DI: 890209590286H4	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 47 Stylet (Obturator) Basic UDI-DI: 890209513080EB	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 48 Huber Infusion set with/without safety features Basic UDI-DI: 890209595010GU	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 49 Over The Needle (OTN) Catheter Basic UDI-DI: 890209513440EK	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 50 Arterial Cannula with/without Safety features Basic UDI-DI: 890209513426ER	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 51 Mini-midline catheter (Peripheral Catheter) Basic UDI-DI: 890209513535EX	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 52 Blood Collection Needle & Holder Basic UDI-DI: 890209588110H8	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 53 Vial Access Spike Basic UDI-DI: 890209513068EM	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 54 Rectal Catheter Basic UDI-DI: 890209530040DY	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; 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
Device 55 HPVD Bottle with /without extension line and trocar Basic UDI-DI: 890209590500GF	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 56 Feeding tubes with/ without Guidewires Basic UDI-DI: 890209540050EE	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 57 Blood Bag (Transfer Bag) Basic UDI-DI: 890209570050FF	☒ Class IIb	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123



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
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Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-18	TSSA/MHS/2024/15 / TPS3023_G10	Initial issue