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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	GCN-SH24080A02	+86 21 6141 0124 Mr. Xiaoxiu Li		2024-05-14	1 of 20

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 038814 0096 Rev. 00

Reference: GCN-SH24080A02

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: CN-MF-000006728

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 038814 0096 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-14

TÜV SÜD Product Service GmbH
Medical and Health Services

Mr. Xiaoxiu Li
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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 **Tracheostomy Tube** **(Basic UDI-DI:** **69449327FA02A01C7, 69449327FA02A02C9)**	☐ 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 038814 0079 Rev. 00; NB# 0123
Device 2 **All Silicone Foley Catheter with Temperature Sensor** **(Basic UDI-DI:** **69449327FF01C00E9, 69449327FF01C01EB)**	☐ 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 Change the device name from “Foley Catheter with Temperature Sensor“ to "All Silicone Foley Catheter with Temperature Sensor” .	☒ Certification as follows: G1 038814 0079 Rev. 00; NB# 0123
Device 3 **Hydrophilic Latex Foley Catheter** **(Basic UDI-DI:** **69449327FF01E07EZ, 69449327FF01E02EP, 69449327FF01E11EQ)**	☐ 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 Change the device name from “Latex Foley Catheter” to “Hydrophilic Latex Foley Catheter” and the “Latex Foley Catheter” under Directives contains “Hydrophilic Latex Foley Catheter” .	☒ Certification as follows: G1 038814 0079 Rev. 00; NB# 0123
Device 4 **Hydrophilic Silicone Foley Catheter** **(Basic UDI-DI:** **69449327FF01E12ES, 69449327FF01E13EU, 69449327FF01E14EW)**	☐ 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 Change the device name from “All Silicone Foley Catheter ” to “Hydrophilic Silicone Foley Catheter” and the “All Silicone Foley Catheter” under Directives contains “Hydrophilic Silicone Foley Catheter” .	☒ Certification as follows: G1 038814 0079 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
	☐ Class III implantable custom-made-device		
Device 5 **Foley Catheter Tray (Basic UDI-DI:** **69449327EA00AB01DV,** **69449327EA00AB02DX,** **69449327EA00AB03DZ,** **69449327EA00AA01DQ, 69449327EA00AA02DS,** **69449327EA00AA03DU,** **69449327EB00AA01E9,** **69449327EB00AA02EB,** **69449327EB00AA03ED,** **69449327EB00BA01EG,** **69449327EB00BA02EJ,** **69449327EB00AD01EQ,** **69449327EB00AD02ES,** **69449327BB00AD03D3)**	☐ 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 Change the device name from "Foley Catheter Kit" to "Foley Catheter Tray" .	☒ Certification as follows: G1 038814 0079 Rev. 00; NB# 0123
Device 6 **Catheterization Pack (Basic UDI-DI:** **69449327AW00WA01TU)**	☐ 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 Change the device name from "Foley Catheter Kit" to "Catheterization Pack" and the "Foley Catheter Kit" under Directives contains "Catheterization Pack" .	☒ Certification as follows: G1 038814 0079 Rev. 00; NB# 0123
Device 7 **Connecting Tube with or without Yankauer Handle (Basic UDI-DI:** **69449327FN01A01H9,** **69449327FN01B01HE,** **69449327FN01A03HD,** **69449327FN01B02HG)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 8 **Nelaton Catheter** **(Basic UDI-DI:** **69449327FF01D00EE)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: G1 038814 0086 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 I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 9 **ETCO2 sampling cannula** **(Basic UDI-DI:** **69449327FR01B02K4,** **69449327FR01B09KJ)**	☐ 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 Change the device name from "O2+CO2 sampling cannula" to "ETCO2 sampling cannula".	☒ Certification as follows: G1 038814 0086 Rev.01; NB# 0123
Device 10 **Tracheal Tube** **(Basic UDI-DI:** **69449327FA01A00BW,** **69449327FA01G01CW,** **69449327FA01A02C2,** **69449327FA01B00C3,** **69449327FA01G09DE,** **69449327FA01B02C7,** **69449327FA01C00C8,** **69449327FA01G02CY,** **69449327FA01C02CC,** **69449327FA01B03C9,** **69449327FA01B08CK,** **69449327FA01C09CS,** **69449327FA01C11CD,** **69449327FA01A10BZ,** **69449327FA01A13C7,** **69449327FA01G03D2,** **69449327FA01A14C9,** **69449327FA01B04CB,** **69449327FA01G10CX,** **69449327FA01B05CD,** **69449327FA01C03CE,** **69449327FA01G11CZ,** **69449327FA01C04CG,** **69449327FA01A11C3)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 11 **PVC Laryngeal Mask Device** **(Basic UDI-DI:**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A "Laryngeal Mask Device" under Directives contains "PVC Laryngeal Mask Device" and "Silicone	☒ Certification as follows: G1 038814 0086 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
69449327FA05B00CX)	☐ 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	Laryngeal Mask Device" under MDR.	
Device 12 **Silicone Laryngeal Mask Device** **(Basic UDI-DI:** **69449327FA05B01CZ,** **69449327FA05B04D7,** **69449327FA05B05D9,** **69449327FA05B07DD,** **69449327FA05B02D3)**	☐ 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 "Laryngeal Mask Device" under Directives contains "PVC Laryngeal Mask Device" and "Silicone Laryngeal Mask Device" under MDR.	☒ Certification as follows: G1 038814 0086 Rev.01; NB# 0123
Device 13 **Intubating Stylet** **(Basic UDI-DI:** **69449327FA04B01CS,** **69449327FA04B00CQ,** **69449327FA04B02CU,)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 14 **Tracheal Tube Introducer (Basic UDI-DI:** **69449327FA04A01CM,** **69449327FA04A02CP,** **69449327FA04A04CT,** **69449327FA04A05CV,** **69449327FA04A03CR)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 15 **Endobronchial Tube (Basic UDI-DI:** **69449327FA03A01CE,** **69449327FA03A02CG)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 038814 0086 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 IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 16 **Endobronchial Blocker Tube** **(Basic UDI-DI: 69449327FA03E00CY)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 17 **ETCO2 Sampling Oxygen Mask** **(Basic UDI-DI: 69449327FR01A10JW, 69449327FR01A09KD, 69449327FR01A11JY, 69449327FR01A12K2)**	☐ 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 Change the device name from “Capnography CO2 Sampling Mask” to “ETCO2 Sampling Oxygen Mask”.	☒ Certification as follows: G1 038814 0086 Rev.01; NB# 0123
Device 18 **Urethral Catheter** **(Basic UDI-DI: 69449327FF01A16EE)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 19 **Stomach Tube** **(Basic UDI-DI: 69449327FN03A02HR, 69449327FN03A01HP)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A "Stomach Tube" under MDR contains "Stomach Tube" and "Silicone Stomach Tube" under Directives.	☒ Certification as follows: G1 038814 0086 Rev.01; NB# 0123; G1 038814 0088 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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 20 **Suction ToothBrush** **(Basic UDI-DI:** **69449327FN04A01HW)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 21 **Bile T-Tube** **(Basic UDI-DI:** **69449327FN01D05HY)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 22 **Intermittent Catheter** **(Basic UDI-DI:** **69449327FF01E00EK)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 23 **Tracheal Tube Kit** **(Basic UDI-DI:** **69449327FA01Z00FT,** **69449327FA01Z03FZ,** **69449327FA01Z02FX,** **69449327FA01Z12G2,** **69449327FA01Z15G8,**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A Change the device name from "Endotracheal Tube Kit" to "Tracheal Tube Kit".	☒ Certification as follows: G1 038814 0086 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
69449327FA01Z14G6)	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 24 **Reinforced Endotracheal Tube** **(Basic UDI-DI:** **69449327FA01E00CJ,** **69449327FA01G12D3,** **69449327FA01E03CQ)**	☐ 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 038814 0086 Rev.01; NB# 0123
Device 25 **Tracheal Tube with Evacuation Lumen (Basic UDI-DI:** **69449327FA01G01CW,** **69449327FA01F01CR)**	☐ 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 Change the device name from "Endotracheal Tube with Evacuation Lumen" to "Tracheal Tube with Evacuation Lumen".	☒ Certification as follows: G1 038814 0086 Rev.01; NB# 0123
Device 26 **Drainage System** **(Basic UDI-DI:** **69449327FN01D02HS,** **69449327FN01D01HQ,** **69449327FN01D03HU,** **69449327FN01E01HV)**	☐ 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 "Drainage System" contains "Silicone Drainage System" under MDR.	☒ Certification as follows: G1 038814 0087 Rev.01; NB# 0123
Device 27 **Oxygen Catheter** **(Basic UDI-DI:** **69449327FR01B00JY,** **69449327FR01B01K2)**	☐ 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 038814 0087 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 III implantable custom-made-device		
Device 28 **Heated Breathing Circuit (Basic UDI-DI:** **69449327FA13A19DC,** **69449327FA13A20CV)**	☐ 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 Change the device name from “Breathing Circuit” to “Heated Breathing Circuit”.	☒ Certification as follows: G1 038814 0087 Rev.01; NB# 0123
Device 29 **Anesthesia Breathing Circuit Kit** **(Basic UDI-DI:** **69449327FA13B00CU,** **69449327FA13B01CW,** **69449327FA13B02CY,** **69449327FA13B03D2,** **69449327FA13B04D4,** **69449327FA13B05D6)**	☐ 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 1. Change the device name from "Anesthetic Breathing Circuit Kit" to "Anesthesia Breathing Circuit Kit". 2. Anesthetic Breathing Circuit included in Anesthesia Breathing Circuit Kit under MDR certificate.	☒ Certification as follows: G1 038814 0087 Rev.01; NB# 0123
Device 30 **Extraction Bag** **(Basic UDI-DI:** **69449327FO02A01HV,** **69449327FO02A02HX,** **69449327FO02A03HZ)**	☐ 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 Change the device name from “ Extraction Bag (Operation Use)” to “ Extraction Bag ”.	☒ Certification as follows: G1 038814 0087 Rev.01; NB# 0123
Device 31 **Ureteral Stent Set** **(Basic UDI-DI:** **69449327FU05A01LY,** **69449327FU05A05M8,** **69449327FU05A02M2,** **69449327FU05A04M6,** **69449327FU05A03M4)**	☐ 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 “Ureteral Stent Set” contains “Ureteral Stent ”under MDR.	☒ Certification as follows: G1 038814 0087 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
Device 32 **Urodynamic Catheter (Basic UDI-DI:** **69449327FU08A01MM,** **69449327FU08A03MR,** **69449327FU08A02MP)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 33 **Ureteral Access Sheath (Basic UDI-DI:** **69449327FU03B01LP)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 34 **Ureteral Dilation Balloon Catheter** **(Basic UDI-DI:** **69449327FU02C00LK)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 35 **Ureteral Dilator** **(Basic UDI-DI:** **69449327FU02B01LG,** **69449327FU02B02LJ)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 36 **Urethral Dilator**	☐ Class III	☒ N/A	☒ Certification as follows: G1 038814 0087 Rev.01;

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: **69449327FU02A05LK,** **69449327FU02A06LM,** **69449327FU02A07LP,** **69449327FU02A08LR)**	☐ 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		NB# 0123
Device 37 **Urological Guide Wire (Basic UDI-DI:** **69449327FU01B07LM,** **69449327FU01B08LP,** **69449327FU01B09LR)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 38 **Percutaneous Nephrostomy Kit** **(Basic UDI-DI:** **69449327FU03A00LG)**	☐ 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 Change the device name from “ Dilation Set” to “ Percutaneous Nephrostomy Kit ”.	☒ Certification as follows: G1 038814 0087 Rev.01; NB# 0123
Device 39 **Stone Retrieval Basket (Basic UDI-DI:** **69449327FU04B01LW)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 40 **Oxygen Tubing** **(Basic UDI-DI:**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 038814 0087 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
69449327FR01C01K7, **69449327FR01C00K5)**	☐ 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 41 **Catheter Mount** **(Basic UDI-DI:** **69449327FA13C00CZ,** **69449327FA13C03D7,** **69449327FA13C04D9,** **69449327FA13C05DB)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 42 **Gas Sampling Line (Basic UDI-DI:** **69449327FA13C02D5,** **69449327FA13C09DK)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 43 **Tube Accessories for Urodynamic Catheter (Basic UDI-DI:** **69449327FU08C01MX)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 44 **Suprapubic Catheter Set (Basic UDI-DI:** **69449327FU07B00MH,** **69449327FU07B01MK,** **69449327FU07B02MM)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 038814 0087 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 IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 45 **Rectal Pressure Catheter (Basic UDI-DI:** **69449327FU08B01MS)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 46 **Suction Evacuation Access Sheath** **(Basic UDI-DI:** **69449327FU04A00LP,** **694493279013004B)**	☐ 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 Change the device name from “ Suction-Evacuation Access Sheath” to “Suction Evacuation Access Sheath ”.	☒ Certification as follows: G1 038814 0087 Rev.01; NB# 0123
Device 47 **Ureteral Catheter** **(Basic UDI-DI:** **69449327FU06A04MD,** **69449327FU06A06MH,** **69449327FU06A05MF,** **69449327FU06A07MK,** **69449327FU06A08MM)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 48 **Suction-Evacuation Nephrostomy Access Sheath Set** **(Basic UDI-DI:** **69449327FU04A02LT)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A Change the device name from “Nephrostomy Access Sheath Set“ to "Suction-Evacuation Nephrostomy Access Sheath Set” .	☒ Certification as follows: G1 038814 0087 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 I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 49 **Urinary Nephrostomy Catheter** **(Basic UDI-DI: 69449327FU07B04MR)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 50 **Vacuum Interrupter** **(Basic UDI-DI: 69449327FN01C01HK)**	☐ 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 038814 0087 Rev.01; NB# 0123
Device 51 **Oxygen Mask** **(Basic UDI-DI: 69449327FR01A00JT, 69449327FR01A01JV)**	☐ 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 038814 0088 Rev.00; NB# 0123
Device 52 **Non-Rebreath Mask (Basic UDI-DI: 69449327FR01A00JT)**	☐ 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 038814 0088 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 53 **Multi-vent Mask** **(Basic UDI-DI:** **69449327FR01A05K5,** **69449327FR01A15K8,** **69449327FR01A06K7,** **69449327FR01A16KA)**	☐ 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 038814 0088 Rev.00; NB# 0123
Device 54 **Suction Catheter** **(Basic UDI-DI:** **69449327FN02A00HE)**	☐ 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 038814 0088 Rev.00; NB# 0123
Device 55 **Nasal Oxygen Cannula (Basic UDI-DI:** **69449327FR01B04K8,** **69449327FR01B05KA)**	☐ 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 038814 0088 Rev.00; NB# 0123
Device 56 **Nebulizer Kit** **(Basic UDI-DI:** **69449327FR01G01KT,** **69449327FR01G04KZ,** **69449327FR01G02KV,** **69449327FR01G03KX,** **69449327FR01F02KQ,** **69449327FR01F03KS,** **69449327FR01F01KN,**	☐ 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 Change the device name from “Aerosol Mask” to “Nebulizer Kit” and the “Nebulizer Kit” under MDR contains “Aerosol Mask” . Change the device name from “Nebulizer” to “Nebulizer Kit” and the “Nebulizer Kit” under MDR contains “Nebulizer” .	☒ Certification as follows: G1 038814 0088 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
69449327FR01F04KU)	☐ Class III implantable custom-made-device		
Device 57 **Disposable Air Cushion Face Mask** **(Basic UDI-DI:** **69449327FA07A00D8,** **69449327FA07A01DA)**	☐ 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 038814 0088 Rev.00; NB# 0123
Device 58 **Nasal Jet Tube** **(Basic UDI-DI:** **69449327FA06A06DD)**	☐ 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 038814 0088 Rev.00; NB# 0123
Device 59 **Feeding Tube** **(Basic UDI-DI:** **69449327FN03C01HZ)**	☐ 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 038814 0088 Rev.00; NB# 0123
Device 60 **Tracheostomy Mask (Basic UDI-DI:** **69449327FR01A08KB)**	☐ 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 038814 0088 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 61 **Oropharyngeal Airway** **(Basic UDI-DI:** **69449327FA06B01D8,** **69449327FA06B02DA)**	☐ 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: G1S 038814 0090 Rev.01; NB# 0123
Device 62 **Nasopharyngeal Airway** **(Basic UDI-DI:** **69449327FA06A01D3,** **69449327FA06A03D7,** **69449327FA06A04D9)**	☐ 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: G1S 038814 0090 Rev.01; NB# 0123
Device 63 **Endoscopic Seal** **(Basic UDI-DI:** **69449327FU04D01M8)**	☐ 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: G1S 038814 0090 Rev.01; NB# 0123
Device 64 **Specimen Collection Bottle** **(Basic UDI-DI:** **69449327FU04C01M3)**	☐ 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 Change the device name from "Stone Collection Bottle" to "Specimen Collection Bottle".	☒ Certification as follows: G1S 038814 0090 Rev.01; NB# 0123

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-14	GCN-SH24080A02	Initial issue