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www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 094928 0004 Rev. 03

Manufacturer:

Bonree Medical Co., Ltd.
No.4 Longzhu Garden, Wanmu Industrial Estate
Nanlang
528451 Zhongshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Oxygen Masks, Aerosol Masks, Multi-vent Masks, Non-Rebreathing Masks, Tracheostomy Masks, Nasal Oxygen Cannulas, Suction Catheters, Stomach Tubes, Feeding Tubes, Yankauer Suction Sets, Endotracheal Tubes, Reinforced Endotracheal Tubes, Endobronchial Tubes, Laryngeal Masks Devices, Intubating Stylets, Endotracheal Tube Introducers(bougie), Guidewires, Nelaton Catheters, Ureteral Stent Sets, Percutaneous Nephrostomy Sets, Ureteral Access Sheaths, Nebulizers, Nasal Oxygen Catheters, Disposable Air Cushion Face Masks, Endotracheal Tubes with Evacuation Lumen, Ureteral Catheters, Intermittent Catheter Kits,Tracheostomy Tubes, Urodynamic catheters, Stone Retrieval Baskets, Urethral Dilators, Ureteral Dilators, Ureteral Dilation Balloon Catheters, Nasal CO_2 Sampling Cannulas, CO2 Sampling and O2 Delivery Masks, Medical Video Endoscopes

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

Report No.: SH191058EXT01

Valid from: 2020-02-10
Valid until: 2024-05-26

Date, 2020-02-10

Christoph Dicks
Head of Certification/Notified Body

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

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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 094928 0004 Rev. 03

Facility(ies):

Bonree Medical Co., Ltd.
No.4 Longzhu Garden, Wanmu Industrial Estate,
Nanlang, 528451 Zhongshan, Guangdong,
PEOPLE'S REPUBLIC OF CHINA

.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 094928 0008 Rev. 00

Manufacturer:

Bonree Medical Co., Ltd.
1st floor of Building No.2
Building No.4, Longzhu Village Economic Estate
Longzhu Avenue
Nanlang
528451 Zhongshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G2 094928 0004 Rev. 03

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 094928 0008 Rev. 00

Report No.: SH23105803

Valid until: 2024-05-26

Issue Date: 2023-12-01

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 094928 0008 Rev. 00

Product Category(ies): **Oxygen Masks, Aerosol Masks, Multi-vent Masks, Non-Rebreathing Masks, Tracheostomy Masks, Nasal Oxygen Cannulas, Suction Catheters, Stomach Tubes, Feeding Tubes, Yankauer Suction Sets, Endotracheal Tubes, Reinforced Endotracheal Tubes, Endobronchial Tubes, Laryngeal Masks Devices, Intubating Stylets, Endotracheal Tube Introducers(bougie), Guidewires, Nelaton Catheters, Ureteral Stent Sets, Percutaneous Nephrostomy Sets, Ureteral Access Sheaths, Nebulizers, Nasal Oxygen Catheters, Disposable Air Cushion Face Masks, Endotracheal Tubes with Evacuation Lumen, Ureteral Catheters, Intermittent Catheter Kits,Tracheostomy Tubes, Urodynamic catheters, Stone Retrieval Baskets, Urethral Dilators, Ureteral Dilators, Ureteral Dilation Balloon Catheters, Nasal CO2 Sampling Cannulas, CO2 Sampling and O2 Delivery Masks, Medical Video Endoscopes**

Description of Change:

Change address from " No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang, 528451 Zhongshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA ." To "1st floor of Building No.2, Building No.4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA ."

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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1st floor of Building No.2
Building No.4, Longzhu Village Economic Estate
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528451 ZHONGSHAN, GUANGDONG
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	713300200/SH24105800_CL	+86 21 6141 0162 Liang.Lu@tuvsud.com		2024-04-10	1 of 15

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 094928 0011 Rev. 02

Reference: 713300200/SH24105800_CL

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-000017844

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 094928 0011 Rev. 02

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-10

TÜV SÜD Product Service GmbH
Medical and Health Services

Mr. Lu Liang
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 **Oropharyngeal Airways** **(Basic UDI -DI: 697209192OPA11JP)**	☐ 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: Certificate # G2S 094928 0002 Rev. 01; NB# 0123
Device 2 **Nasopharyngeal Airways** **(Basic UDI -DI: 697209192NPA12JE)**	☐ 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: Certificate # G2S 094928 0002 Rev. 01; NB# 0123
Device 3 **Rectal Catheters** **(Basic UDI -DI: 697209192RTC24M7)**	☐ 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: Certificate # G2S 094928 0002 Rev. 01; NB# 0123
Device 4 **Nelaton Catheters** **(Basic UDI -DI: 697209192NLTN23QX** **697209192NLTL23QM)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G2 094928 0004 Rev. 03; 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 5 **Disposable electronic ureteroscope** **(Basic UDI -DI: 697209192ETU34KM)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 6 **Ureteral Access Sheaths** **(Basic UDI -DI: 697209192UAS27LR)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 7 **Guidewires** **(Basic UDI -DI: 697209192GDWH19KC** **697209192GDWP19LL** **697209192GDWZ19N6)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 8 **Endotracheal Tubes**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: Certificate # G2 094928 0004 Rev. 03; 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
(Basic UDI -DI: 697209192ETTU13R2 **697209192ETTC13N8)**	☐ 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 9 **Endotracheal Tube with Evacuation Lumen** **(Basic UDI -DI: 697209192ETE31GX)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 10 **Reinforced Endotracheal Tubes** **(Basic UDI -DI: 697209192RETU14R8** **697209192RETC14NE)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 11 **Tracheostomy Tubes** **(Basic UDI -DI: 697209192TTTU35XF** **697209192TTTC35UM** **697209192RTTU35WM** **697209192RTTC35TT** **697209192TTE35NC)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 12	☐ 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
Endotracheal Tube Introducers(bougie)/Intubating Stylets **(Basic UDI -DI: 697209192ETI17HR** **697209192IBS17GR)**	☐ 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		Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 13 **Oxygen Masks** **(Basic UDI -DI: 697209192OGM01JH)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 14 **Nebulizer with Aerosol Masks** **(Basic UDI -DI: 697209192ASM02GD)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 15 **Multi-vent Masks** **(Basic UDI -DI: 697209192MVM03M8)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; 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 16 **Non-Rebreathing Masks** **(Basic UDI -DI: 697209192NBM04H9)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 17 **Yankauer Suction Sets** **(Basic UDI -DI: 697209192YSS10RJ)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 18 **Suction Catheters** **(Basic UDI -DI: 697209192STC07MJ)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 19 **Stomach Tubes** **(Basic UDI -DI: 697209192SMT08NQ)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; 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 20 **Feeding Tubes** **(Basic UDI -DI: 697209192FDT09GC)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 21 **Nasal Oxygen Cannulas** **(Basic UDI -DI: 697209192NOC06JN)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 22 **Laryngeal Mask Devices** **(Basic UDI -DI: 697209192LMDP16MD** **697209192LMDS16MU)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 23 **Tracheostomy Masks** **(Basic UDI -DI: 697209192TTM05PB)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 094928 0004 Rev. 03; 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 24 **Endobronchial Tubes** **(Basic UDI -DI: 697209192EBTL15HK** **697209192EBTR15JH)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 25 **Ureteral Stent Sets** **(Basic UDI -DI: 697209192USS25QK)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 26 **Percutaneous Nephrostomy Sets (Basic UDI -DI: 697209192PNS26MT)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; 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 27 **Disposable Air Cushion Face Masks (Basic UDI -DI: 697209192ACM30D2)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 28 **Ureteral Catheters (Basic UDI -DI: 697209192UTC32N7)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 29 **Stone Retrieval Baskets (Basic UDI -DI: 697209192SRB37M8)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 30 **Urethral Dilators (Basic UDI -DI: 697209192UHD39L6)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; 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 31 **Ureteral Dilators (Basic UDI -DI: 697209192UED38KF)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 32 **Nasal CO_2 Sampling Cannulas (Basic UDI -DI: 697209192CO2C41CM)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 33 **CO_2 Sampling and O_2 Delivery Masks (Basic UDI -DI: 697209192CO2M42E9)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 34 **Nasal Oxygen Catheters (Basic UDI -DI: 697209192NOC29K2)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 094928 0004 Rev. 03; 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 35 **Intermittent Catheter Kits (Basic UDI -DI: 697209192ICK33FN)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 36 **Urodynamic Catheters (Basic UDI -DI: 697209192UD2C36GD** **697209192UD3C36GL)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 37 **Ureteral Dilation Balloon Catheters (Basic UDI -DI: 697209192UDBC40KD)**	☐ 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: Certificate # G2 094928 0004 Rev. 03; NB# 0123
Device 38 **100% Silicone Foley Catheters**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 094928 0003 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
(Basic UDI -DI: 697209192SFCS21MU **697209192SFCC21KC** **697209192SFCD21KH** **697209192SFCM21LW** **697209192SFCT21MZ)**	☒ 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		

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	☒ 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
2023/10/25	713300200	Initial issue
2024/03/05	713300200/SH24105800_CL	Change CL: addition of devices #23 to #38
2024/04/10	713300200/SH24105800_CL	Correction of address sequence