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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD 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 038814 0087 Rev. 01

Manufacturer:

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Drainage System, Oxygen Catheter, Silicone Drainage System, Breathing Circuit, Anesthetic Breathing Circuit, Anesthetic Breathing Circuit Kit, Rectal Pressure Catheter, Extraction Bag (Operation Use), Ureteral Stent Set, Urodynamic Catheter, Ureteral Access Sheath, Ureteral Dilation Balloon Catheter, Ureteral Stent, Ureteral Dilator, Urethral Dilator, Urological Guide Wire, Suction-Evacuation Access Sheath, Dilation Set, Stone Retrieval Basket, Ureteral Catheter, Urinary Nephrostomy Catheter, Oxygen Tubing, Catheter Mount, Gas Sampling Line, Tube Accessories for Urodynamic Catheter, Suprapubic Catheter Set, Nephrostomy Access Sheath Set, Oxygen Adaptor, Vacuum Interrupter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 038814 0087 Rev. 01

Report No.: SH2008002

Valid from: 2021-02-19

Valid until: 2024-05-26

Date, 2021-02-19

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate, Hualong
511434 PANYU, GUANGZHOU
PEOPLE'S REPUBLIC OF CHINA

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

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**Well Lead Medical Co., Ltd.**
Manufacturer address and contact details	C-4 Jinhu Industrial Estate, Hualong, 511434 Panyu, Guangzhou, People's Republic of China
Single Registration Number (SRN) (if available)	CN-MF-000006728

Authorised Representative name (if applicable)	**Shanghai International Holding Corp. GmbH (Europe)**
Authorised Representative address and contact details	Eiffestraβe 80, 20537 Hamburg, GERMANY
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	**TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany** **□ See attached schedule**
Notified body number (if applicable)	CE0123 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Directive Certificate number(s) to which this confirmation is made (if applicable)	**G1 038814 0079 Rev.00** **G1 038814 0086 Rev.01** **G1 038814 0087 Rev.01** **G1 038814 0088 Rev.00** **G1S 038814 0090 Rev.01** □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☑ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

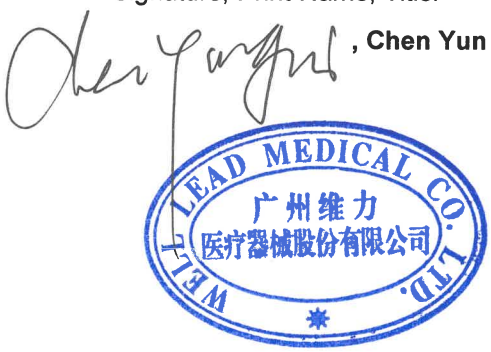
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: **Well Lead Medical Co., Ltd.**

Location & Date: **Guangzhou, 2023-11-7**

Signature, Print Name, Title:



, Chen Yun Gui, Management Representative & PRRC

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Foley Catheter with Temperature Sensor	**G1 038814 0079 Rev.00**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
All Silicone Foley Catheter	**G1 038814 0079 Rev.00**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	BSI Group The Netherlands B.V. (Address: Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Notified Body) CE 2797	2028-12-31	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Latex Foley Catheter	**G1 038814 0079 Rev.00**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	BSI Group The Netherlands B.V. (Address: Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Notified Body) CE 2797	2028-12-31	
Reinforced Endotracheal Tube	**G1 038814 0086 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Endotracheal Tube Kit	**G1 038814 0086 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	

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Intubating Stylet	**G1 038814 0086 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Endobronchial Tube	**G1 038814 0086 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Oxygen Catheter	**G1 038814 0087 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	

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Nasal Oxygen Cannula	**G1 038814 0088 Rev.00**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Silicone Drainage System	**G1 038814 0087 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Drainage System	**G1 038814 0087 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	

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Extraction Bag (Operation Use)	**G1 038814 0087 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Laryngeal Mask Device	**G1 038814 0086 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Aerosol Mask	**G1 038814 0088 Rev.00**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	

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Nebulizer	**G1 038814 0088 Rev.00**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Oxygen Tubing	**G1 038814 0087 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Oxygen Mask	**G1 038814 0088 Rev.00**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	

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Non-Rebreath Mask	**G1 038814 0088 Rev.00**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Oropharyngeal Airway	**G1S 038814 0090 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Suprapubic Catheter Set	**G1 038814 0087 Rev.01**	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	