Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 038814 0079 Rev. 00

Manufacturer:

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

Product Category(ies): **Latex Foley Catheter, All Silicone Foley Catheter, Foley Catheter with Temperature Sensor, Foley Catheter Kit, Tracheostomy Tube**

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. See also notes overleaf.

Report No.: SH19080CN01

Valid from: 2020-03-31

Valid until: 2024-05-26

Date, 2020-03-31

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

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate
Hualong Panyu
Guangzhou
Guangdong
511434
China

23 May 2024

Notified Body Confirmation Letter
Reference: EU2023-607/874023

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has 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 following manufacturer:

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate
Hualong Panyu
Guangzhou
Guangdong
511434
China

SRN Number (if available): 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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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, by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

NB 2797

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
Latex Foley Catheter	Class IIb excluding Class IIb implantable non-WET	N/A	#G1 038814 0079 REV. 00 NB# 0123
All Silicone Foley Catheter	Class IIb excluding Class IIb implantable non-WET	N/A	#G1 038814 0079 REV. 00 NB# 0123
Prefilled syringe with purified water or glycerin solution	Class I device placed on the market in sterile condition	N/A	#G1S 038814 0090 Rev. 01 NB# 0123
Spigot	Class I device placed on the market in sterile condition	N/A	#G1S 038814 0090 Rev. 01 NB# 0123
Urine Meter	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	#G2MS 18 03 38814 069 NB# 0123
Urine Bag	Class I device placed on the market in sterile condition	N/A	#G1S 038814 0089 Rev. 00 NB# 0123

Confirmation Letter Revision History

Date	Action
2024/05/23	Initial issue

NB 2797

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**

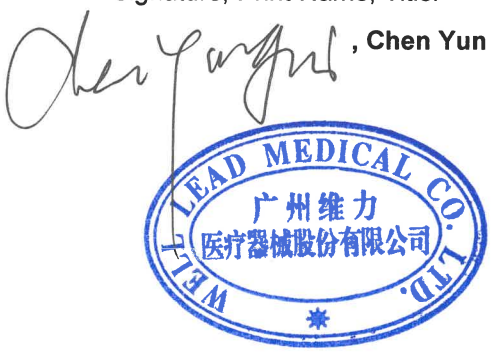
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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	

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)
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	

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)
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	

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)
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	

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)
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	

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)
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	