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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 038814 0092 Rev. 02

Manufacturer:

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

SRN Manufacturer - CN-MF-000006728

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 038814 0092 Rev. 02

Report No.: SH2408002

Preceding Certificate No.: G10 038814 0092 Rev. 01

Valid from: 2026-02-03
Valid until: 2028-05-15

Date of Initial Issuance: 2023-05-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-02-03

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No. G10 038814 0092 Rev. 02

Classification:	Class IIa
Device Group:	A019013 - PERCUTANEOUS NEEDLES
Intended Purpose:	/

Classification:	Class IIa
Device Group:	A060101 - VACUUM AND GRAVITY DRAINAGE SYSTEMS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES
Intended Purpose:	/

Classification:	Class IIa
Device Group:	A99 - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION - OTHER
Intended Purpose:	/

Classification:	Class IIa
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R010101 - NASOPHARYNGEAL TUBES
Intended Purpose:	/

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Classification:	Class IIa
Device Group:	R010201 - LARYNGEAL MASKS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R010301 - ENDOTRACHEAL TUBES, CUFFLESS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R010302 - ENDOTRACHEAL TUBES, CUFFED
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R010380 - ENDOTRACHEAL TUBES - ACCESSORIES
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R010401 - ENDOBRONCHIAL TUBES, RIGHT
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R010402 - ENDOBRONCHIAL TUBES, LEFT
Intended Purpose:	/

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Classification:	Class IIa
Device Group:	R010499 - ENDOBRONCHIAL TUBES - OTHER
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R020101 - STANDARD BREATHING CIRCUITS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R020107 - THERMOREGULATED BREATHING CIRCUITS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R020299 - MOUNT CATHETERS - OTHER
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R028099 - RESPIRATORY CIRCUITS AND MOUNT CATHETERS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R030101 - VENTILATION MASKS
Intended Purpose:	/

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Classification:	Class IIa
Device Group:	R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R030103 - AEROSOL THERAPY MASKS AND SYSTEMS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R040101 - ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	R040102 - ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS HUMIDIFIERS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U010105 - URETHRAL PROSTATIC AND BLADDER CATHETERS, NELATON
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U020302 - DOUBLE LOOP URETERAL STENTS
Intended Purpose:	/

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Classification:	Class IIa
Device Group:	U030101 - SEQUENTIAL DILATORS FOR PERCUTANEOUS NEPHROSTOMY
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U030102 - URETHRAL AND URETERAL DILATORS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U030202 - URETERAL DILATORS, WITH BALLOON
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U040101 - KITS WITH DRAINAGE CATHETERS, DIRECT PUNCTURE
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U040102 - KITS WITH DRAINAGE CATHETERS AND INTRODUCERS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U040199 - DEVICES FOR SUPRAPUBIC URINARY DRAINAGE - OTHER
Intended Purpose:	/

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Classification:	Class IIa
Device Group:	U050301 - URETHRAL PRESSURE PROFILE CATHETERS WITHOUT BALLOON
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U0599 - URODYNAMICS DEVICES - OTHER
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U0601 - UROLOGICAL GUIDEWIRES, HYDROPHILIC
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U0602 - UROLOGICAL GUIDEWIRES, NOT HYDROPHILIC
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U090101 - URINARY STONE RETRIEVAL BASKETS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	U090399 - SINGLE-USE INSTRUMENTS FOR UROGENITAL ENDOSCOPY - OTHER
Intended Purpose:	/

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The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2023-05-16	SH21080MDR01	Initial issuance
01	2023-12-12	SH2308001	Supplemented: Device(s)/group of device(s) added
02	2026-02-03	SH2408002	Supplemented: Device(s)/group of device(s) added

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