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

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 0095 Rev. 01

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 0095 Rev. 01

Report No.: SH2408002

Preceding Certificate No.: G10 038814 0095 Rev. 00

Valid from: 2026-02-03
Valid until: 2028-12-05

Date of Initial Issuance: 2023-12-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-02-03

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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No. G10 038814 0095 Rev. 01

Classification:	Class IIb
Device Group:	G020201 - NASOGASTRIC INTESTINAL TUBES
Intended Purpose:	Feeding tubes are used for administration of medicine, liquids or enteral feeding by means of a syringe or tubing. They are inserted through the nose or mouth.

Classification:	Class IIb
Device Group:	G020202 - GASTRO-JEJUNOSTOMY, TUBES AND SETS
Intended Purpose:	A Gastrostomy tube is a tube inserted through a small incision in the abdomen into the stomach and is used for long term or short-term enteral nutrition and medication.

Classification:	Class IIb
Device Group:	R010501 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED
Intended Purpose:	The Tracheostomy Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through an incision in the trachea (the windpipe).

Classification:	Class IIb
Device Group:	R010502 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED
Intended Purpose:	The Tracheostomy Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through an incision in the trachea (the windpipe).

Classification:	Class IIb
Device Group:	U010299 - URETHRAL PROSTATIC AND BLADDER CATHETERS, WITH BALLOON - OTHER
Intended Purpose:	1) Foley Catheter Tray contain a foley catheter and all the necessary accessories which are required for successful urinary catheterization. 2) Hydrophilic Latex Foley Catheter is inserted into the bladder through urethra and are indicated for routine urine drainage or for routine post operative drainage and irrigation bladder. 3) Hydrophilic Silicone Foley Catheter is intended to be used by trained person or healthcare professionals for transurethral or suprapubic drainage. The 3-way model can be used for irrigation of the bladder.

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Classification:	Class IIb
Device Group:	U0103 - URETHRAL PROSTATIC AND BLADDER CATHETERS WITH TEMPERATURE SENSORS
Intended Purpose:	All Silicone Foley Catheter with Temperature Sensor is passed through the urethra during urinary catheterization and into the bladder to drain urine, the temperature sensor can be used to monitor the bladder temperature during drainage to assist clinical diagnosis. It is intended for temperature monitoring in patients that are catheterized because of fluid management problems, evaluation of urinary output, urine clearance following surgery or trauma involving pelvic organs, or obstruction and paralysis. MRI compatible.
Classification:	Class IIb
Device Group:	U040203 - NEPHROSTOMY CATHETERS
Intended Purpose:	The urinary drainage catheter is typically used for urine drainage from bladder or kidney. It has wings that secure it within the cavity.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2023-12-06	SH2308001	Initial issuance
01	2026-02-03	SH2408002	Supplemented: Device(s)/group of device(s) added

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