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. 00

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 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:G10 038814 0095 Rev. 00

Report No.: SH2308001
Valid from: 2023-12-06
Valid until: 2028-12-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-12-06

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. 00

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:	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.
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

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