



Product Service

Certificate

No. Q5 038814 0085 Rev. 01

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

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Medical Devices**
(for detailed information see next pages)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH2008001
Valid from: 2020-07-28
Valid until: 2022-08-19

Date, 2020-07-28

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Well Lead Medical Co., Ltd.
C-4 Jinhui Industrial Estate, Hualong, 511434 Panyu, Guangzhou,
PEOPLE'S REPUBLIC OF CHINA

Well Lead Medical Co., Ltd.
No. 47 Guomao Avenue South, 511434 Panyu, Guangzhou,
PEOPLE'S REPUBLIC OF CHINA

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

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**Design and Development, Production and Distribution of Medical Devices: All
 Silicone Foley Catheter, Foley Catheter with Temperature Sensor, Foley Catheter
 Kit, Latex Foley Catheter, Urethral Catheter, Connecting Tube with or without
 Yankauer Handle, Silicone Stomach Tube, Nelaton Catheter, Silicone Tube,
 Suction ToothBrush, Capnography CO2 Sampling Mask, O2+CO2 Sampling
 Cannula, Bile T-Tube, Intermittent Catheter, Oxygen Mask, Non-Rebreath Mask,
 Multi-vent Mask, Stomach Tube, Suction Catheter, Feeding Tube, Nasal Oxygen
 Cannula, Urethral Catheter without Balloon, Tracheostomy Mask, Aerosol Mask,
 Nebulizer, Drainage System, Oxygen Catheter, Silicone Drainage System,
 Breathing Circuit, Urine Meter, Urine Bag, Spigot, Prefilled Syringe with Purified
 Water or Glycerin Solution, Tracheostomy Tube, Tracheal Tube, Endotracheal
 Tube Kit, Reinforced Endotracheal Tube, Endotracheal Tube with Evacuation
 Lumen, Laryngeal Mask Device, Intubating Stylet, Endotracheal Tube Introducer,
 Endobronchial Tube, Endobronchial Blocker Tube, Disposable Air Cushion Face
 Mask, Nasal Jet Tube, Cricothyrotomy Kit, Anesthetic Breathing Circuit,
 Anesthetic Breathing Circuit Kit, Oropharyngeal Airway, Nasopharyngeal Airway,
 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, Guide Wire, Suction-
 Evacuation Access Sheath, Dilation Set, Stone Retrieval Basket, Ureteral
 Catheter, Endoscopic Seal, Urinary Nephrostomy Catheter, Catheter Holder,
 Breathing Bag, Laryngoscope Blade, Male External Catheter, Surgical Face
 Mask, Medical Face Mask**