



Certificate

No. Q5 038814 0085 Rev. 02

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). 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:Q5 038814 0085 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_038814_0085_Rev_02)

Report No.: SH2008002

Valid from: 2021-02-19

Valid until: 2022-08-19

Date, 2021-02-19



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 Jinhu Industrial Estate, Hualong, 511434 Panyu, Guangzhou,
 PEOPLE'S REPUBLIC OF CHINA

Production of All Silicone Foley Catheter, Foley Catheter with
 Temperature Sensor, Foley Catheter Kit, Latex Foley Catheter,
 Urethral Catheter, Silicone Stomach Tube, Silicone Tube, Suction
 Tooth Brush, Bile T-Tube, Stomach Tube, Urethral Catheter
 without Balloon, Drainage System, Silicone Drainage System,
 Breathing Circuit, Prefilled Syringe with Purified Water or Glycerin
 Solution, Endotracheal Tube Kit, Reinforced Endotracheal Tube,
 Laryngeal Mask Device, Endobronchial Blocker Tube, Disposable
 Air Cushion Face Mask, Anesthetic Breathing Circuit, Anesthetic
 Breathing Circuit Kit, Rectal Pressure Catheter, Extraction Bag
 (Operation Use), Endoscopic Seal, Urinary Nephrostomy Catheter,
 Breathing Bag, Male External Catheter, Stone Collection Bottle,
 Catheter Mount, Gas Sampling Line, Suprapubic Catheter Set,
 Oxygen Adaptor, Vacuum Interrupter

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

Design and Development, Production and Distribution of 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 Tooth
 Brush, 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 Dilator
 Balloon Catheter, Ureteral Stent, Ureteral Dilator, Urethral Dilator,
 Urological Guide Wire, Suction-Evacuation Access Sheath,
 Dilator Set, Stone Retrieval Basket, Ureteral Catheter,
 Endoscopic Seal, Urinary Nephrostomy Catheter, Catheter Holder,



Product Service

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Breathing Bag, Laryngoscope Blade, Male External Catheter, Surgical Face Mask, Medical Face Mask, Stone Collection Bottle, Oxygen Tubing, Catheter Mount, Gas Sampling Line, Tube Accessories for Urodynamic Catheter, Suprapubic Catheter Set, Nephrostomy Access Sheath Set, Oxygen Adaptor, Vacuum Interrupter

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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, Urological 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, Stone Collection Bottle, Oxygen Tubing, Catheter Mount, Gas Sampling Line, Tube Accessories for Urodynamic Catheter, Suprapubic Catheter Set, Nephrostomy Access Sheath Set, Oxygen Adaptor, Vacuum Interrupter