



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 038814 0087 Rev. 01

Manufacturer:

Well Lead Medical Co., Ltd.

C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Drainage System, Oxygen Catheter, Silicone Drainage System, Breathing Circuit, Anesthetic Breathing Circuit, Anesthetic Breathing Circuit Kit, 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, Urinary Nephrostomy Catheter, Oxygen Tubing, Catheter Mount, Gas Sampling Line, Tube Accessories for Urodynamic Catheter, Suprapubic Catheter Set, Nephrostomy Access Sheath Set, Oxygen Adaptor, Vacuum Interrupter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. 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:G10388140087Rev.01

Report No.: SH2008002

Valid from: 2021-02-19

Valid until: 2024-05-26

Date, 2021-02-19

Christoph Dicks
Head of Certification/Notified Body



Product Service

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

Report No.: SH2008002

Valid from: 2021-02-19

Valid until: 2022-08-19

Date, 2021-02-19

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 038814 0085 Rev. 02

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 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,

Certificate

No. Q5 038814 0085 Rev. 02

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



Product Service

Certificate

No. Q5 038814 0085 Rev. 02

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