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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 038814 0085 Rev. 05

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of Non-active devices for anaesthesia, emergency and intensive care(for detailed information see next pages)

Design and Development, Production and Distribution of Active medical devices
Portable Roller Irrigation pump, Vibrating Mesh Nebulization System

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, 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:Q5 038814 0085 Rev. 05

Report No.:	SH25008001
Valid from:	2025-08-20
Valid until:	2028-08-19

Date, 2025-06-03

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Production of Non-active devices for anaesthesia, emergency and intensive care
Sterile All Silicone Foley Catheter, Sterile Foley Catheter with Temperature Sensor, Sterile Foley Catheter Kit, Sterile Latex Foley Catheter, Sterile Urethral Catheter, Sterile Silicone Stomach Tube, Non-sterile Silicone Tube, Sterile Tooth Brush for professional use , Sterile Bile T-Tube, Sterile Urethral Catheter without Balloon, Non-sterile Breathing Circuit, Sterile Prefilled Syringe with Purified Water or Glycerin Solution, Sterile Endotracheal Tube Kit, Sterile Reinforced Endotracheal Tube, Sterile Laryngeal Mask Device, Sterile Endobronchial Blocker Tube, Sterile and Non-sterile Anaesthetic Face Mask, Sterile and Non-sterile Anesthetic Breathing Circuit, Sterile and Non-sterile Anesthetic Breathing Circuit Kit, Sterile Rectal Pressure Catheter, Sterile Endoscopic Seal, Sterile Urinary Nephrostomy Catheter, Sterile and Non-sterile Breathing Bag , Non-sterile Male External Catheter, Sterile Specimen Collection Bottle , Sterile and Non-sterile Catheter Mount, Sterile Suprapubic Catheter Set, Sterile Vacuum Interrupter, Sterile Drainage System, Sterile Silicone Drainage System, Sterile Irrigation Tubing Set, Sterile Gastrostomy tube, Sterile Ureteral Stent Set, Sterile Ureteral Stent
Production of Active medical devices
Portable Roller Irrigation pump, Vibrating Mesh Nebulization System

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Facility(ies):

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 Non-active devices for anaesthesia, emergency and intensive care
Sterile All Silicone Foley Catheter, Sterile Foley Catheter with Temperature Sensor, Sterile Foley Catheter Kit, Sterile Latex Foley Catheter, Sterile Urethral Catheter, Sterile and Non-sterile Connecting Tube with or without Yankauer Handle, Sterile Silicone Stomach Tube, Sterile Nelaton Catheter, Non-sterile Silicone Tube, Sterile Tooth Brush for professional use, Sterile and Non-sterile Capnography CO_2 Sampling Mask, Sterile and Non-sterile O_2+CO_2 Sampling Cannula, Sterile Bile T-Tube, Sterile Intermittent Catheter, Non-sterile Oxygen Mask, Non-sterile Non-Rebreath Mask, Sterile and Non-sterile Multi-vent Mask, Sterile Stomach Tube, Sterile Suction Catheter, Sterile Feeding Tube, Non-sterile Nasal Oxygen Cannula, Sterile Urethral Catheter without Balloon, Sterile Tracheostomy Mask, Sterile and Non-sterile Aerosol Mask, Sterile and Non-sterile Non Active Nebulizer Kit (without Nebulizer), Sterile Oxygen Catheter, Non-sterile Breathing Circuit, Sterile Urine Meter, Sterile and Non-sterile Urine Bag, Sterile and Non-sterile Catheter Spigot, Sterile Prefilled Syringe with Purified Water or Glycerin Solution, Sterile Tracheostomy Tube, Sterile Tracheal Tube, Sterile Endotracheal Tube Kit, Sterile Reinforced Endotracheal Tube, Sterile Endotracheal Tube with Evacuation Lumen, Sterile Laryngeal Mask Device, Sterile Intubating Stylet, Sterile Endotracheal Tube Introducer, Sterile Endobronchial Tube, Sterile Endobronchial Blocker Tube, Sterile and Non-sterile Anaesthetic Face Mask, Sterile Nasal Jet Tube, Sterile Cricothyrotomy Kit, Sterile and Non-sterile Anesthetic Breathing Circuit, Sterile and Non-sterile Anesthetic Breathing Circuit Kit, Sterile and Non-sterile Oropharyngeal Airway, Sterile Nasopharyngeal Airway, Sterile Rectal Pressure Catheter, Sterile Extraction Bag (Operation Use), Sterile Ureteral Stent Set, Sterile Urodynamic Catheter, Sterile Ureteral Access Sheath, Sterile Ureteral Dilation Balloon Catheter, Sterile Ureteral Stent, Sterile Ureteral Dilator, Sterile Urethral Dilator, Sterile Urological Guide Wire, Sterile Suction-Evacuation Access Sheath, Sterile Percutaneous Nephrostomy Kit , Sterile Stone Retrieval Basket, Sterile Ureteral Catheter, Sterile Endoscopic Seal, Sterile Urinary Nephrostomy Catheter, Non-sterile Catheter Holder, Sterile and Non-sterile Breathing Bag , Sterile Laryngoscope Blade, Non-sterile Male External Catheter, Sterile Specimen Collection Bottle , Sterile and Non-sterile Oxygen Tubing, Sterile and Non-sterile Catheter Mount, Sterile and Non-sterile Gas Sampling Line, Sterile Tube Accessories for Urodynamic Catheter, Sterile Suprapubic Catheter Set, Sterile Nephrostomy Access Sheath Set, Sterile Oxygen Adaptor, Sterile Vacuum Interrupter, Sterile Central Venous Catheter Set, Sterile Nephrostomy Introduction Needle, Non-sterile Urine Bag Hanger, Non-sterile Urine Meter Hook, Sterile Drainage System, Sterile Silicone Drainage System, Non-sterile Surgical Face Mask, Non-sterile Medical Face Mask, Sterile Irrigation Tubing Set, Sterile Needle Guide, Sterile Hydrophilic Intermittent Catheter, Sterile Gastrostomy tube
Design and Development, Production and Distribution of Active devices
Portable Roller Irrigation pump, Vibrating Mesh Nebulization System

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Sterile All Silicone Foley Catheter, Sterile Foley Catheter with Temperature Sensor, Sterile Foley Catheter Kit, Sterile Latex Foley Catheter, Sterile Urethral Catheter, Sterile and Non-sterile Connecting Tube with or without Yankauer Handle, Sterile Silicone Stomach Tube, Sterile Nelaton Catheter, Non-sterile Silicone Tube, Sterile Tooth Brush for professional use, Sterile and Non-sterile Capnography CO_2 Sampling Mask, Sterile and Non-sterile O_2+CO_2 Sampling Cannula, Sterile Bile T-Tube, Sterile Intermittent Catheter, Non-sterile Oxygen Mask, Non-sterile Non-Rebreath Mask, Sterile and Non-sterile Multi-vent Mask, Sterile Stomach Tube, Sterile Suction Catheter, Sterile Feeding Tube, Non-sterile Nasal Oxygen Cannula, Sterile Urethral Catheter without Balloon, Sterile Tracheostomy Mask, Sterile and Non-sterile Aerosol Mask, Sterile and Non-sterile Non Active Nebulizer Kit (without Nebulizer), Sterile Oxygen Catheter, Non-sterile Breathing Circuit, Sterile Urine Meter, Sterile and Non-sterile Urine Bag, Sterile and Non-sterile Catheter Spigot, Sterile Prefilled Syringe with Purified Water or Glycerin Solution, Sterile Tracheostomy Tube, Sterile Tracheal Tube, Sterile Endotracheal Tube Kit, Sterile Reinforced Endotracheal Tube, Sterile Endotracheal Tube with Evacuation Lumen, Sterile Laryngeal Mask Device, Sterile Intubating Stylet, Sterile Endotracheal Tube Introducer, Sterile Endobronchial Tube, Sterile Endobronchial Blocker Tube, Sterile and Non-sterile Anaesthetic Face Mask, Sterile Nasal Jet Tube, Sterile Cricothyrotomy Kit, Sterile and Non-sterile Anesthetic Breathing Circuit, Sterile and Non-sterile Anesthetic Breathing Circuit Kit, Sterile and Non-sterile Oropharyngeal Airway, Sterile Nasopharyngeal Airway, Sterile Rectal Pressure Catheter, Sterile Extraction Bag (Operation Use), Sterile Ureteral Stent Set, Sterile Urodynamic Catheter, Sterile Ureteral Access Sheath, Sterile Ureteral Dilation Balloon Catheter, Sterile Ureteral Stent, Sterile Ureteral Dilator, Sterile Urethral Dilator, Sterile Urological Guide Wire, Sterile Suction-Evacuation Access Sheath, Sterile Percutaneous Nephrostomy Kit , Sterile Stone Retrieval Basket, Sterile Ureteral Catheter, Sterile Endoscopic Seal, Sterile Urinary Nephrostomy Catheter, Non-sterile Catheter Holder, Sterile and Non-sterile Breathing Bag , Sterile Laryngoscope Blade, Non-sterile Male External Catheter, Sterile Specimen Collection Bottle , Sterile and Non-sterile Oxygen Tubing, Sterile and Non-sterile Catheter Mount, Sterile and Non-sterile Gas Sampling Line, Sterile Tube Accessories for Urodynamic Catheter, Sterile Suprapubic Catheter Set, Sterile Nephrostomy Access Sheath Set, Sterile Oxygen Adaptor, Sterile Vacuum Interrupter, Sterile Central Venous Catheter Set, Sterile Nephrostomy Introduction Needle, Non-sterile Urine Bag Hanger, Non-sterile Urine Meter Hook, Sterile Drainage System, Sterile Silicone Drainage System, Non-sterile Surgical Face Mask, Non-sterile Medical Face Mask, Sterile Irrigation Tubing Set, Sterile Needle Guide, Sterile Hydrophilic Intermittent Catheter, Sterile Gastrostomy tube

Design and Development, Production and Distribution of Active medical devices
Portable Roller Irrigation pump, Vibrating Mesh Nebulization System