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

Product Service

Certificate

No. Q5 038814 0070 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:

tuv-sud.com/ps-cert

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.: SH1908022

Valid from: 2020-01-29

Valid until: 2022-08-19

Date, 2020-01-29

Christoph Dicks
Head of Certification/Notified Body

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

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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

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

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Detailed Product Category(ies):

Urethral Catheter and Tracheal Tube, Tracheostomy Tube, Oropharyngeal Airway, Connecting Tube with Yankauer Handle, Suction Catheter, Stomach Tube, Oxygen Mask, Intubating Stylet, Feeding Tube, Nasal Specula, All Silicone Foley Catheter, Silicone Stomach Tube, Nasal Oxygen Cannula, Multi-vent Mask, Laryngeal Mask Device, Endobronchial Tube, Non-Rebreath Mask, Tracheostomy Mask, Aerosol Mask, Nelaton Catheter, Reinforced Endotracheal Tube, Endotracheal Tube Introducer, Foley Catheter with Temperature Sensor, Disposable Rectal Tube, Nasopharyngeal Airway, Nebulizer, Disposable Air Cushion Face Mask, Foley Catheter Kit, Endotracheal Tube Kit, HMEF(Heat and Moisture Exchanger Filter), Drainage System, Oxygen Catheter, Silicone Tube, Endobronchial Blocker Tube, Extraction Bag (Operation Uses), Urine Bag, Spigot, Ureteral Stent Set, Silicone Drainage System, Endotracheal Tube with Evacuation Lumen, Tracheostomy Tube with Inner Cannula, Prefilled Syringe with Lubricating Jelly, Disposable Self-Catheterization System, Prefilled Syringe with Purified Water or Glycerin Solution, Capnography CO2 Sampling Mask, O2+CO2 Sampling Cannula, Catheter Holder, Breathing Bag, Percutaneous Tracheostomy Tube Kit, Suction ToothBrush, Bile T-Tube, Fecal Management System, Urine Meter, Intermittent Catheter, Laryngoscope Blade, Gastrostomy Tube, Ureteral Access Sheath, Ureteral Dilation Balloon Catheter, Urodynamic Catheter, Rectal Pressure Catheter, Anesthetic Breathing Circuit, Male External Catheter, Dilation Set, Suction-Evacuation Access Sheath, Bladder Puncture Fistula, Guide Wire, Nasal Jet Tube, Urethral Catheter without Balloon, Stone Retrieval Basket, Ureteral Catheter, Esophageal-tracheal Combitube, Single Lumen Endobronchial Tube, Urethral Dilator, Ureteral Dilator, Ureteral Stent, PU Foley Catheter, Endoscopic Seal, Breathing Circuit, Endobronchial Blocker Tube Kit, Anesthetic Breathing Circuit Kit, Urinary Nephrostomy Catheter, Cricothyrotomy Kit

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