



Product Service

CERTIFICATE

No. Q1N 16 05 38814 061

Holder of Certificate: **Well Lead Medical Co., Ltd.**

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

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



Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution
of Medical Devices**
(For detailed information see attachment)

**Applied
Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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.: SH1608018

Valid from: 2016-09-06
Valid until: 2019-08-19

Date, 2016-09-05

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Attachment for Certificate No Q1N 16 05 38814 061

Supplement 001 dated 2016-09-05



Product Service

For the product(s)/product category (ies):

Design and Development, Production and Distribution of Urethral Catheters and Tracheal Tubes, Tracheostomy Tubes, Oropharyngeal Airways, Suction Catheters, Nasal Speculas, Connecting Tubes with Yankauer Handle, Urine Meters, Stomach Tubes, Intubating Stylets, Suction Tubes of Oral Care, All Silicone Foley Catheters, All Silicone Stomach Tubes, Nasal Oxygen Cannulas, Fecal Management Systems, Laryngeal Mask Devices, Tracheobronchial Tubes, Non-Rebreath Masks, Tracheostomy Masks, Oxygen Masks, Nelaton Catheters, Reinforced Endotracheal Tubes, Endotracheal Tube Introducers, Disposable Rectal Tubes, Foley Catheters with Temperature Sensor, Nebulizers, Nasopharyngeal Airways, Stylets, Foley Catheter Kits, Disposable Air Cushion Face Masks, Endotracheal Tube Kits, Oxygen Catheters, HMEF(Heat and Moisture Exchanger Filters), Silicone Tubes, Manual Resuscitators, Drainage Systems, Feeding Tubes, Endobronchial Blocker Tubes, Laryngoscope Blades, Extraction Bags (Operation Uses), Clip-Its(Lens Implantation), Spigots, Ureteral Stent Sets, Self Hydrophilic Catheters, Silicone Drainage Systems, Aerosol Masks, Urine Bags, Endotracheal Tubes with Evacuation Lumen, Bile T-Tubes, Tracheostomy Tubes with Inner Cannula, Multi-vent Masks, Prefilled Syringes with Lubricating Jelly, Disposable Self-Catheterization Systems, Prefilled Syringes with Purified Water or 10% Glycerin Solution Capnography CO2 Sampling Masks, O2+CO2 Sampling Cannulas, Non-invasive Positive Pressure Ventilation Masks, Catheter Holders, Breathing Bags, Tracheostomy Tube Kits, Gastrostomy Tubes, Ureteral Access Sheaths, Ureteral Dilation Balloon Catheters, Extracorporeal Circulation Conduct of Blood Purification Apparatus, Urodynamic Catheters, Rectal Pressure Catheters, Anesthetic Breathing Circuits, Male External Catheters, Dilation Sets, Suction-Evacuation Access Sheaths, Bladder Puncture Fistula, Guide Wire, Nasal Jet Tubes, Urethral Catheters without Balloon, Stone Retrieval Baskets, Urethral Catheters

Munich, MHS-CRT, 2016-09-05

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