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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 038814 0073 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):

**Disposable and Reusable,
Plastic and Rubber Devices for Anesthesia,
Respiratory, Urology, Hemodialysis and
Surgical Drainage Treatment.
(for detailed information see next pages)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19080EXT01

Valid from: 2019-08-07

Valid until: 2024-05-26

Date, 2019-08-07

Stefan Preiß
Head of Certification/Notified Body



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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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



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Detailed Product Category(ies):

Urethral Catheters and Tracheal Tubes, Nelaton Catheters, Connecting Tubes with Yankauer Handle, Intubating Stylets, Laryngeal Mask Devices, Tracheobronchial Tubes, Reinforced Endotracheal Tubes, Nebulizers, Oxygen Masks, Non-Rebreath Masks, Tracheostomy Masks, Aerosol Masks, Multi-vent Masks, Endotracheal Tube Introducers, Nasal Oxygen Cannulas, Stylets, Disposable Air Cushion Face Masks, Endotracheal Tube Kits, HMEF(Heat and Moisture Exchanger Filters), Manual Resuscitators, Drainage Systems, Oxygen Catheters, Silicone Tubes, Endobronchial Blocker Tubes, Extraction Bags(Operation Use), Ureteral Stent Sets, Silicone Drainage Systems, Endotracheal Tubes with Evacuation Lumen, Suction Catheters, Feeding Tubes, Stomach Tubes, Silicone Stomach Tubes, Disposable Self-Catheterization Systems, Capnography CO2 Sampling Mask, O2+CO2 Sampling Cannula, Non-invasive Positive Pressure Ventilation Masks, Suction Tubes of Oral Care, Bile T-Tubes, Fecal Management Systems, Self Hydrophilic Catheters, Ureteral Access Sheaths, Ureteral Dilation Balloon Catheters, Extracorporeal Circulation Conduct of Blood Purification Apparatus, Urodynamic Catheters, Rectal Pressure Catheters, Anesthetic Breathing Circuits, Dilation Sets, Suction-Evacuation Access Sheaths, Bladder Puncture Fistula, Guide Wire, Nasal Jet Tubes, Urethral Catheters without Balloon, Stone Retrieval Baskets, Ureteral Catheters, Esophageal-tracheal Combitubes, Single Lumen Endobronchial Tubes, Urethral Dilators, Ureteral Dilators, Ureteral Stents, PU Foley Catheter