

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 15 05 38814 058

Manufacturer:

Well Lead Medical Co., Ltd.

C-4 Jinhu Industrial Estate, Hualong

511434 Panyu, Guangzhou

PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding

Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg GERMANY

Product Category(ies):

For detailed information see attachment

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.:

SH15080EXT01

Valid from:

2015-08-24

Valid until:

2020-08-23

H.- J.

Date, 2015-06-15

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123 Page 1 of 3





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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.

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

No 47 Guomao Avenue South, 511434 Panyu, Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Supplement 001 dated 2015-06-15

Attachment for Certificate No G2 15 05 38814 058

For the product(s)/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,

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**

Endotracheal Tubes with Evacuation Lumen, Suction Catheters, Feeding Tubes,

Capnography CO₂ Sampling Masks, O₂+ CO₂ Sampling Cannulas,

Stomach Tubes, Silicone Stomach Tubes, Disposable Self-Catheterization Systems,

Munich, CRT2, 2015-06-15

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