



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 15 05 38814 058

**Manufacturer:** **Well Lead Medical Co., Ltd.**  
 C-4 Jinhua 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



**Date,** 2015-06-15

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**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****Facility(ies):**

**Well Lead Medical Co., Ltd.**  
**C-4 Jinhua 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**

Attachment for Certificate No G2 15 05 38814 058

Supplement 001 dated 2015-06-15



Product Service

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,  
 Endotracheal Tubes with Evacuation Lumen, Suction Catheters, Feeding Tubes,  
 Stomach Tubes, Silicone Stomach Tubes, Disposable Self-Catheterization Systems,  
 Capnography CO<sub>2</sub> Sampling Masks, O<sub>2</sub>+ CO<sub>2</sub> Sampling Cannulas,  
 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

Munich, CRT2, 2015-06-15

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