ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-CERTIFICATE

Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 10 06 38814 032

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):
**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, Parker Flex-It Stylets,
Disposable Air Cushion Face Masks,
Foley Catheter Kits, Endotracheal Tube Kits,
Disposable Breathing Circuits,
HMEF(Heat and Moisture Exchanger Filters),
Manual Resuscitators, Drainage Systems,
Oxygen Catheters, Sillcone 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**

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 products / product categories according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

Report No.: SH1008011
Valid until: 2015-08-23

Date, 2010-08-24

Hans-Heiner Junker

TÜV SÜD 398757

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

TÜV®

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EC-Certificate
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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

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