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Zentralstelle der Länder  
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bei Arzneimitteln und  
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Product Service

# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 038814 0086 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):** Urethral Catheter, Connecting Tube with or without Yankauer Handle, Silicone Stomach Tube, Nelaton Catheter, Suction ToothBrush, Capnography CO2 Sampling Mask, O2+CO2 Sampling Cannula, Bile T-Tube, Intermittent Catheter, Tracheal Tube, Endotracheal Tube Kit, Reinforced Endotracheal Tube, Endotracheal Tube with Evacuation Lumen, Laryngeal Mask Device, Intubating Stylet, Endotracheal Tube Introducer, Endobronchial Tube, Endobronchial Blocker Tube

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10388140086Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G10388140086Rev.01)

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**Date,** 2021-02-19

Christoph Dicks  
Head of Certification/Notified Body