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Zentralstelle der Länder  
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bei Arzneimitteln und  
Medizinprodukten  
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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 0079 Rev. 00**

**Manufacturer:** **Well Lead Medical Co., Ltd.**  
C-4 Jinhu Industrial Estate, Hualong  
511434 Panyu, Guangzhou  
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):** **Latex Foley Catheter, All Silicone Foley Catheter,  
Foley Catheter with Temperature Sensor, Foley  
Catheter Kit, Tracheostomy 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. See also notes overleaf.

**Report No.:** SH19080CN01

**Valid from:** 2020-03-31

**Valid until:** 2024-05-26

**Date,** 2020-03-31

Christoph Dicks  
Head of Certification/Notified Body

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT