Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 0087 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):

Drainage System, Oxygen Catheter, Silicone Drainage System, Breathing Circuit, Anesthetic Breathing Circuit, Anesthetic Breathing Circuit Kit, Rectal Pressure Catheter, Extraction Bag (Operation Use), Ureteral Stent Set, Urodynamic Catheter, Ureteral Access Sheath, Ureteral Dilation Balloon Catheter, Ureteral Stent, Ureteral Dilator, Urethral Dilator, Urological Guide Wire, Suction-Evacuation Access Sheath, Dilation Set, Stone Retrieval Basket, Ureteral Catheter, Urinary Nephrostomy Catheter

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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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