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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 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