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 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.

STERIL ROMANIA S.R.L. 2 BUCUREȘTI - ROMÂNIA

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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A4 / 07.17