ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 15 05 38814 057

Manufacturer:

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

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Tracheostomy Tubes, Urethral Catheters, All Silicone Foley Catheters, Foley Catheters with Temperature Sensor, Tracheostomy Tubes with Inner Cannula, Prefilled Syringes with Lubricating Jelly, Foley Catheter Kits, Tracheostomy Tube Kits, Gastrostomy Tubes

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.: SH15080EXT01

Valid from: 2015-09-07
Valid until: 2020-09-06

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Date, 2015-06-15

Hans-Heiner Junker

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

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Facility(ies):

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

Well Lead Medical Co., Ltd.
No 47 Guomao Avenue South, 511434 Panyu, Guangzhou, PEOPLE'S REPUBLIC OF CHINA

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