



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 0088 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): Oxygen Mask, Non-Rebreath Mask, Multi-vent Mask, Stomach Tube, Suction Catheter, Feeding Tube, Nasal Oxygen Cannula, Urethral Catheter without Balloon, Tracheostomy Mask, Aerosol Mask, Nebulizer, Disposable Air Cushion Face Mask, Nasal Jet Tube, Cricothyrotomy Rit 57

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