



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 049076 0016 Rev. 03

Manufacturer:

Shenzhen Creative Industry Co., Ltd.

Floor 5, BLD 9

BaiWangxin High-Tech Industrial Park

Songbai Road, Xili Street

Nanshan District

518110 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry, Central Monitoring System

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10490760016Rev.03

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Date, 2021-04-06

Christoph Dicks

Head of Certification/Notified Body