



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 085381 0005 Rev. 00

Manufacturer:

Shenzhen Himed Co., Ltd.

East 4th Floor
Baocheng Technology Building Majialong
Industry Area, Nanshan District
518052 Shenzhen City, Guangdong
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies): Pulse Oximeter Probe,
CO2 Sampling Lines,
Temperature Probe

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.:

SH18804EXT01

Valid from:

2018-12-19

Valid until:

2023-12-18

Date, 2018-09-04

Stefan Preiß



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 085381 0005 Rev. 00

Facility(ies):

Shenzhen Himed Co., Ltd.
East 4th Floor, Baocheng Technology Building Majialong, Industry
Area, Nanshan District, 518052 Shenzhen City, Guangdong,
PEOPLE'S REPUBLIC OF CHINA