

ificate

ance System

Medical Devices (MDD), Annex II excluding (4) or III)

31 002



Product Service

Shenzhen Greatmade Tech limited

3rd Floor, Building B
Baifuli Industrial Zone, Shanghenglang
Huahui Road, Dalang Street
Longhua New District
518109 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA



Prolix GmbH

Brehmstr. 56
40239 Duesseldorf
GERMANY

Spo2 sensor

TUV SUD Product Service GmbH declares that the aforementioned system has implemented a quality assurance system for design, manufacture and final testing of the devices / device categories in accordance with MDD Annex II. The system conforms to the requirements of this Directive and is subject to the requirements for the marketing of class III devices an additional Annex II (4) certificate is issued overleaf.

GZ1728501

2018-04-11
2023-04-10

Stefan Preiß



GmbH is Notified Body with identification no. 0123

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 17 12 02231 002

Facility(ies):

Shenzhen Greatmade Tech limited
3rd Floor, Building B, Baifuli Industrial Zone, Shanghenglang,
Huahui Road, Dalang Street, Longhua New District, 518109
Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF
CHINA



Product Service

CERTIFICATE

No. Q1N 17 12 02231 001

Holder of Certificate: Shenzhen Greatmade Tech limited

3rd Floor, Building B
Baifuli Industrial Zone, Shanghenglang,
Huahui Road, Dalang Street
Longhua New District

518109 Shenzhen, Guangdong Province
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Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF
CHINA

Certification Mark:



Scope of Certificate: Design and Development and Distribution of SpO2 Patient cable and lead

Applied Standard(s):

EN ISO 13485:2012 + AC:2013
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2013)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

The Certification Body of TÜV SÜD Product Service GmbH certifies that the holder of the certificate above has established and is maintaining a quality management system in accordance with the requirements of the listed standard(s). See also notes overleaf.

Report No.:

GZ1728501

Valid from:

2018-04-11

Valid until:

2021-04-10

Date, 2018-04-11

Stefan Preiß

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