Product Service

ficate

ance System

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

231 002

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

e: **Prolinx GmbH**
Brehmstr. 56
40239 Duesseldorf
GERMANY

Spo2 sensor

ÜV SÜD Product Service GmbH declares that the aforementioned
nted a quality assurance system for design, manufacture and final
e devices / device categories in accordance with MDD Annex II.
em conforms to the requirements of this Directive and is subject to
marketing of class III devices an additional Annex II (4) certificate
es overleaf.

GZ1728501

2018-04-11
2023-04-10

04052768523761

Stefan Preiß

GmbH is Notified Body with identification no. 0123

Digitally signed by Grabazei Alexandru
Date: 2019.10.24 15:52:41 EEST
Reason: MoldSign Signature
Location: Moldova

mbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

A1 / 07.09

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 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

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

DAkkS CRT2 / 10.13

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

CERTIFICATE

No. Q1N 17 12 02231 001

Holder of Certificate: Shenzhen Greatma
3rd Floor, Building B
Baifuli Industrial Zone, Shang
Huahui Road, Dalang Street
Longhua New District
518109 Shenzhen, Guangdo
PEOPLE'S REPUBLIC OF C

Facility(ies): Shenzhen Greatmade Tech
3rd Floor, Building B, Baifuli
Shanghenglang, Huahui Roa
Longhua New District, 5181
Guangdong Province, PEOP
CHINA

Certification Mark:

Scope of Certificate: Design and Developm
and Distribution of Sp
Patient cable and lead

Applied Standard(s): EN ISO 13485:2012 + AC:20
Medical devices - Quality ma
Requirements for regulatory
(ISO 13485:2003 + Cor. 1:2
DIN EN ISO 13485:2012
Upgrade required until 2019-

The Certification Body of TÜV SÜD Product Service GmbH cert
above has established and is maintaining a quality managemen
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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