

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

Manufacturer: 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



EC-Representative: Prolinx GmbH

Brehmstr. 56
40239 Duesseldorf
GERMANY

Product Category(ies): Spo2 sensor

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.: GZ1728501

Valid from: 2018-04-11
Valid until: 2023-04-10

Date, 2018-04-11

S. Preiß
Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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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Product Service

CERTIFICATE

No. Q1N 17 12 02231 001

Holder of Certificate: Shenzhen Greatmade Tech limited

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Huahui Road, Dalang Street
Longhua New District
518109 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

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Longhua New District, 518109 Shenzhen,
Guangdong Province, PEOPLE'S REPUBLIC OF
CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production
and Distribution of Spo2 sensor,
Patient cable and leadwire, Blood pressure cuff

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets 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

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