

CERTIFICAT

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CERTIFICATE

ZERTIFIKAT

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## 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

Prolinx GmbH EC-Representative:

Brehmstr. 56 40239 Duesseldorf

GERMANY

Product

Category(ies):

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.

Spo2 sensor

Report No.: GZ1728501

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

Date, 2018-04-11 Stefan Preiß

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

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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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and Distribution of Spo2 sensor,

Patient cable and leadwire, Blood pressure cuff

Applied

EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -

Requirements for regulatory purposes

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

Report No.:

Valid from:

2021-04-10

GZ1728501



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Date. 2018-04-11

TÜV SÜD Product Service GmbH + Zertifizierstelle - Ridlerstraße 65 - 80339 München - Germany

## 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 PEOPLE'S REPUBLIC OF CHINA

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

Certification Mark:

Facility(ies):



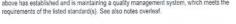




Standard(s):

(ISO 13485:2003 + Cor. 1:2009) DIN EN ISO 13485:2012

Upgrade required until 2019-03-31



Valid until:







