

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

Spo2 sensor

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.

Report No .:

GZ1728501

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

Date, 2018-04-11

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

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

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CERTIFICAT CERTIFICADO СЕРТИФИКАТ .



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

CERTIFICADO • CEPTUФИКАТ • CERTIFICATE

CERTIFICAT

and Distribution of Spo2 sensor,

Patient cable and leadwire, Blood pressure cuff

Applied

EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned

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

ZERTIFIKAT

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CERTIFICATE

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



ZERTIFIKAT







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

CERTIFICATE

No. Q1N 17 12 02231 001

Certification Mark:

Facility(ies):



Scope of Certificate: Design and Development, Production

Standard(s):

Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)

DIN EN ISO 13485:2012 Upgrade required until 2019-03-31



