



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

**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. Preis*  
Stefan Preis



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

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**Facility(ies):**

Shenzhen Greatmade Tech limited  
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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

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

**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



**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

*S. Preis*  
Stefan Preis



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 Skype : Greatmade01

**Reusable/Disposable NIBP Cuff and Air Hose  
 ( Updated on April ,2012)**

**NIBP CUFF**

Greatmade P/N	Description ( Cable , Connector )	Unit Price
CF001A	Neonate <b>Single tube</b> NIBP cuff , 6-11cm Arm Circumference	
CF002A	Infant <b>single tube</b> NIBP cuff , 10-19cm Arm Circumference	
CF003A	Child <b>single tube</b> NIBP cuff , 18-26cm Arm Circumference	
CF004A	Adult <b>single tube</b> NIBP cuff , 25-35cm Arm Circumference	
CF004LA	Large <b>Adult Single</b> Tube Nibp Cuff , 33-47cm Arm Circumference	
CF004TA	THIGH <b>Single Tube</b> Nibp Cuff , 46-66cm Arm Circumference	

**NIBP Cuff**

Greatmade P/N	Description ( Cable , Connector )	Unit Price
CF001B	Neonate <b>Dual tube</b> NIBP cuff , 6-11cm Arm Circumference	
CF002B	Infant <b>dual tube</b> NIBP cuff , 10-19cm Arm Circumference	
CF003B	Child <b>dual tube</b> NIBP cuff ,18-26cm Arm Circumference	
CF004B	Adult <b>dual tube</b> NIBP cuff , 25-35cm Arm Circumference	
CF004LB	Large Adult <b>Dual Tube</b> Nibp Cuff , 33-47cm Arm Circumference	
CF004TB	THIGH <b>Dual tube</b> NIBP Cuff,46-66cm Arm Circumference	

**Adult Longer Type**

CF004XL-A	Adult Long Single tube Nibp Cuff , 33-47cm Arm circumference ,L 690mm*W 145mm	
CF004XL-B	Adult Long Dual tube Nibp Cuff ,33-47cm Arm Circumference .	