



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:

2018-04-11

Valid until:

2023-04-10

405276852376

Stefan Preiß

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

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

CERTIFICAT

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ZERTIFIKAT

CERTIFICAT CERTIFICADO • CEPTUФИКАТ •



CERTIFICAT

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CERTIFICADO

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СЕРТИФИКАТ

CERTIFICAT

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ZERTIFIKAT

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

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

TUV



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

Certification Mark:



Scope of Certificate: Design and Development, Production

and Distribution of Spo2 sensor,

Patient cable and leadwire, Blood pressure cuff

Applied

EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -Standard(s):

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 2018-04-11

2021-04-10

Valid from: Valid until:

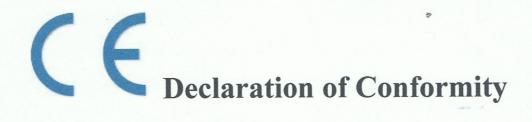
Date, 2018-04-11

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

TUV®



According to the Medical Devices Directive 93/42/EEC		
Manufacturer's Name :	HK Greatmade Tech Ltd	
Manufacturer's Address:	6th floor ,B Building ,ShuiDou New Village , LongHua town .	
	Shenzhen City, Guang Dong Prov	rince, China
Product:	Non-Invasive Blood Pressure Cuff and Air Hose	
Type Designation/Trademark:	N.I.B.P cuff, Class I	
Product Part No. Of Manufacturer: CF001A,CF002A,CF003A,CF004A,CF004F004TB,CF001C,CF002C,CF003C,CF004F004LD,CF004TD,CF005,CF005-1.5,CF008,CF009,CF010,CF011,CF012,CF013,CF0021,CF022,CF023-BK,CF023-BK-P,CF023-V,CF004LA-V,CF004TA-V,CF001B-V,CF00CF1101A/B,CF1102A/B,CF1103A/B,CF11110A/B,CF1111A/B,CF1112A/B,CF1113A/A/B/C/D,CF1205A/B/C/D,CF1207A/B/C/D,B/C/D,CF1212A/B/C/D,CF1213A/B/C/D,CF1601A/B,CF1602A/B,CF1603A/B,CF1906M,BP12,BP15,BP17,BP18,BP20,NIBP-H,NAuthorized representative established with Company Name:	C,CF004LC,CF004TC,CF001D,CF00 D5N,CF006,CF006N,CF006-,CF007L D14,CF015,CF016,CF017,CF017B,C B-BL,CF023-BL-P,CF001A-V,CF002A 02B-V,CF003B-V,CF004B-V,CF004L 04A/B,CF1105A/B,CF1107A/B,CF11 /B,CF1201AB/C/D,CF1202A/B/C/D,CC CF1208A/B/C/D,CF1209A/B/C/D,CF F1501A/B,CF1502A/B,CF1503A/B,CI 1C,CF1901I,CF1901N,BP04,BP05,B NIBP-S,NIBP-Y,NIBP-D.	02D,CF003D,CF004D,C .,CF007B,CF007N,CF00 F018,CF019,CF020,CF A-V,CF003A-V,CF004A- LB-V,CF04TB-V, 08A/B,CD1109A/B,CF1 CF1203A/B/C/D,CF1204 1210A/B/C/F,CF1211A/ F1504A/B,CF1505A/B,C
Company Address:		
Person responsible for making this declar	ration	
Name, Surname:	ZhangHanzhi	
Position/Title:	Director, Owner	
Hereby we declares that the Medical requirements listed in the Annex I of Shen zhom. China Them Han Thi	device as indicated above confo the European Medical Device D	rms with the essential Directive 93/42/EEC
(Place) (Company stamp and legal signature)		(Date)

Declaration of Conformity According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name:

HK Greatmade Tech Limited

Manufacturer's Address:

3th, B Building ,BaifuliIndustrial Zone,Shanghenglang

village, LongHua town.

Shenzhen City, Guang Dong Province, China

Product:

Patient Monitor cable and lead, Class I

Type Designation/Trademark:

Patient Monitor cable with leadwires

Product Part No. Of Manufacturer: MC001A-3,MC001B-3, MC001B-5, MC001A-5, MC002A-3, MC002B-3, MC002C-3,MC002D-3, MC003A-5, MC003B-5, MC003C-5, MC003D-5,MC004A-3, MC004B-3, MC005A-5, MC005B-5, MC006A, MC006B, MC007A, MC007B, MC007C, MC007D,MC008, MC009A, MC009B, MC010A,MC010B, MC013-3, MC015-5, MC017A-5, MC017B-5, MC018A-3, MC018B-3,MC019A-3, MC019B-3, MC019C-3,MC019D-3, MC020A-5, MC020B-5, MC020C-5, MC020D-5, MC021A-3,MC021B-3,MC022A-5,MC022B-5,MC023A-3,MC023B-3,MC023C-3,MC023D-3,MC024A-5, MC024B-5,MC024C-5,MC024D-5,MC025A/B/C/D/E/F/G/H-3,MC026A/B/C/D/E/F/G/H-5,MC027-3, MC028-5,MC029A-3,MC029B-3,MC030A-3,MC030B-3,MC031-5,MC032A-5,MC032B-5,MC033A-3, MC033B-3,MC034A-3,MC034B-3, MC035B-5,MC036A,MC036B, MC037A-3, MC037B-3, MC038A-5, MC038B-5,MC039-5, MC041A, MC042A-3,MC042B-3, MC043A-5, MC043B-5,MC044-3, MC045.MC046-3,MC046-5,MC047-3,MC047-5,MC048-3,MC048-5,MC049,MC050,MC051.MC052A,MC052B,MC053-3,MC053-5,MC054-3,MC054-5,MC055,MC056,MC057-4AS,MC057-4IS,MC065-3,MC065-5,MC066,MC067,MC068,MC069-3AS/5AS,MC069-3IG/5IG,

Authorized representative established within the EU (if applicable):

Company Name:

Prolinx GmbH

Company Address:

Brehmstr. 56,40239, Duesseldorf, Germany

Person responsible for making this declaration

Name, Surname:

ZhangHanzhi

Position/Title:

Director, Owner

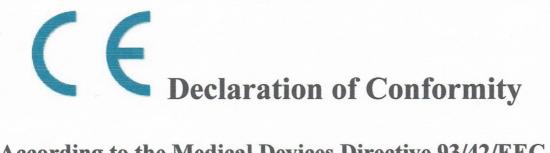
Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC

(Place)

Mar 19th ,2018

(Company stamp and legal signature)

(Date)



According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name: HK Greatmade Tech Limited Manufacturer's Address: 3th, B Building ,Baifuli Industiral Zone,shanghenglang village, LongHua town. Shenzhen City, Guang Dong Province, China Product: Non-Invasive Blood Pressure Cuff and Air Hose N.I.B.P cuff, Class I **Type Designation/Trademark:** Product Part No. Of Manufacturer: CF001A, CF002A, CF003A, CF004A, CF004LA, CF004TA, CF001B,CF002B,CF003B, CF004B, CF004LB, CF004TB, CF001C,CF002C,CF003C,CF004C, CF004LC,CF004TC,CF005,CF006.CF007A,CF007B,CF008,CF009,CF010,CF011.CF012,CF013,C F014,CF015,CF016 ,CF1601A/B,CF1602A/B ,CF1701A,CF1702B,CF006-H ,CF017,CF018,CF019 CF020, CF1501A/B,CF1502A/B,CF1503A/B, CF1504A/B, CF1505A/B, CF1506A/B, CF1507A/B, CF1508A/B,CF1509A/B,CF1510A/B,CF1512A/B,CF1101A,CF1102A,CF1103A,CF1104A,CF1105 A,CF1106A/B,CF1107A/B,CF108A/B,CF1109A/B,CF1110A/B,CF1111A/B,CF1112A/B.CF1601A/ B,CF1602A/B,CF1603A/B,CF1701-500A/A1,CF1701-1000A/A1,CF1701-3000A/A1,CF1701-500A1 -BL,CF1701-1000A1-BL,CF1701-3000A1-BL,CF1801,CF021,CF022,CF023,CF025,CF026 Authorized representative established within the EU (if applicable): Company Name: **Prolinx GmbH** Company Address: Brehmstr. 56,40239, Duesseldorf, Germany Person responsible for making this declaration ZhangHanzhi Name, Surname: Position/Title: Director, Owner

Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC

Mar 19th,2018

(Place)

(Company stamp and legal signature)

(Date)