Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech LTD**
Manufacturer's Address :	**6th,Building C,PinchuangYuan Science Technology Park, ShuiDou New Village, LongHua Town ,Shenzhen ,China.**
Product :	**Spo2 Sensor, Class I B**
Type Designation/Trademark :	**adult finger clip Sensor**

Product Part No. Of Manufacturer:

AF001-3 ,AF001-1 ,AF001-3D,AF002 ,AF004-3 ,AF005-1 ,AF005-3 ,AF006 ,AF007-1 ,AF007-3 ,AF008-3 ,AF008-1,AF009 ,AF051 ,AF039,AF012 ,AF013-1 ,AF023 ,AF024-1A ,AF024-1B ,AF024-2 ,AF024-3 AF024-1-OXI,AF024-3-OXI,AF024-OXI-GE,AF032-1,AF032-3,AF036,AF037,AF022-3,AF022-1,AF052,A F025,AF026,AF026-3,AF027,AF029,AF028,AF016,AF018,AF017,AF019,AF020,AF021,AF022-1,AF022-3,AF028,AF030,AF031,AF040,AF041,AF043,AF048,AF049,AF050,AF051,AF052,AF056 ,AF057 ,AF058, AF053,AF054,AF056,AF059,AF060,AF061,AF062,AF063,AF064-N/M.AF065,AF066,AF067,AF068,AF06 9,AF070,AF071,AF072,AF073,AF074,AF075,AF076,AF077,AF078,AF079,AF080,AF081,AF082,AF083,A F084,AF085,AF086,AF087,AF088,AF089,AF090,AF091,AF092,AF093,AF094,AF095,AF096,AF097,AF0 98,AF015-3,AF022-1,AF072,AF100,AF100-GE,AF101,AF102,AF103

Authorized representative established within the EU (if applicable):

Company Name :

Company Address :

Person responsible for making this declaration

Name, Surname :	**ZhangHanzhi**
Position/Title :	**Director/ Owner**

Hereby 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.

Shenzhen, China

Zhang Hanzhi

(Place)

Dec 24th,2012

(Date)

(Company stamp and legal signature)

Digitally signed by Grabazei Alexandru
Date: 2020.05.23 11:17:03 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Stefan Preiß

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

A1 / 07.09

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

DAkkS CRT2 / 10.13

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

Declaration of Conformity

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 Province , 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,CF004LA,CF004TA,CF001B,CF002B,CF003B,CF004B,CF004LB,CF004TB,CF001C,CF002C,CF003C,CF004C,CF004LC,CF004TC,CF001D,CF002D,CF003D,CF004D,CF004LD,CF004TD,CF005,CF005-1.5,CF005N,CF006,CF006N,CF006-,CF007L,CF007B,CF007N,CF008,CF009,CF010,CF011,CF012,CF013,CF014,CF015,CF016,CF017,CF017B,CF018,CF019,CF020,CF021,CF022,CF023-BK,CF023-BK-P,CF023-BL,CF023-BL-P,CF001A-V,CF002A-V,CF003A-V,CF004A-V,CF004LA-V,CF004TA-V,CF001B-V,CF002B-V,CF003B-V,CF004B-V,CF004LB-V,CF04TB-V,
CF1101A/B,CF1102A/B,CF1103A/B,CF1104A/B,CF1105A/B,CF1107A/B,CF1108A/B,CD1109A/B,CF1110A/B,CF1111A/B,CF1112A/B,CF1113A/B,CF1201AB/C/D,CF1202A/B/C/D,CF1203A/B/C/D,CF1204A/B/C/D,CF1205A/B/C/D,CF1207A/B/C/D,CF1208A/B/C/D,CF1209A/B/C/D,CF1210A/B/C/F,CF1211A/B/C/D,CF1212A/B/C/D,CF1213A/B/C/D,CF1501A/B,CF1502A/B,CF1503A/B,CF1504A/B,CF1505A/B,CF1601A/B,CF1602A/B,CF1603A/B,CF1901C,CF1901I,CF1901N,BP04,BP05,BP07,BP09-MF,BP09-MM,BP12,BP15,BP17,BP18,BP20,NIBP-H,NIBP-S,NIBP-Y,NIBP-D.

Authorized representative established within the EU (if applicable):

Company Name :

Company Address :

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

Shenzhen China

Zhang Han zhi

Jan 21th, 2014

(Place) **(Date)**

(Company stamp and legal signature)

CE

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech Limited**
Manufacturer's Address :	**4th floor ,A Building ,Pinchuangyuan science technology park ,Shuidou New Village , LongHua town Shenzhen City , Guang Dong Province , China**
Product :	**Spo2 sensor ,Class I B**
Type Designation/Trademark :	**Disposable sensor**

Produc Part No.Of Manufacturer: DS024-N/A ,DS024-I/A,DS024-A/A,DS024-P/A,DS024-A/B,DS024-N/B DS024-I/B,DS024-P/B,DS024-P/C,DS024-A/C,DS024-A/C,DS024-FA,DS024-FA-P,DS024-A/D,OXI-DS024-N/A, OXI-DS024-I/A,OXI-DS024-A/A,OXI-DS024-P/A,OXI-DS024-D/B,OXI-DS024-N/B,OXI-DS024-I/B,OXI-DS024-P/B,OXI-DS024-P/C,OXI-DS024-A/C.OXI-DS024-A/D,OXI-DS024-FA-A,OXI-DS024-FA-P,DS005-N/A,DS005-N/A,DS005-A/A,DS005-P/A,DS005-D/B,DS005-N/B,DS005-I/B ,DS005-P/B,DS005-P/C,DS005-A/C,DS005-FA,DS005-FA-P,DS005-A/D,DS022-N/A,DS022-I/A,DS022-A/A,DS022-P/A,DS022-D/B,DS022-A /B,DS022-I/B,DS022-P/B,DS022-P/C,DS022-A/C,DS022-FA,DS022-FA,DS022-A/D,DS032-N/A,DS032-I/A,DS032-A/A,DS032-A/A,DS032-D/ B,DS032-A/B,DS032-A/B,DS032-P/B,DS032-P/C,DS032-A/C,DS032-FA,DS032-FA-P,DS001-N/A,DS001-I/A,DS001-A/A,DS022-P/A,DS001-D/B,DS001-A/B,DS001-I/B,DS001-P/B,DS001-P/C,DS001-A/C,DS001-A/D,DS001-FA,,DS001-FA-P,DS051-N/A,DS051-I/A,DS051-A/A,DS051-P/A,DS051-N/A-GE,DS051-N/A-GE,DS051-A/A-GE,DS051-P/A-GE,DS051-D/B,DS051-A/B,DS051-I/B,DS051-P/B,DS051-D/B –GE,DS051-D/B –GE,DS051-I/B-GE,DS051-P/B-GE,DS051-P/C,DS051-A/C,DS051-P/C-GE,DS051-A/C-GE,DS051-FA,DS051-FA-P,DS051-FA-GE,DS051-FA-P-GE,DS007-N/A,DS007-I/A,DS007-A/A,DS007-P/A,DS007-D/B,DS007-A/B,DS007-I/B,DS007-P/B,DS007-P/C,DS007-A/C,DS007-D/ A,DS007-FA,DS007-FA-P,DS060-N/A,DS060-I/A,DS060-A/A,DS060-P/A,DS060-D/B,DS060-A/B,DS060-I/B,DS060-P/B,DS060-P/C,DS060-A /C,DS060-A/DDS060-FA,DS060-FA-P,DS014-N/A,DS014-I/A,DS014-A/A,DS014-P/A,DS014-A/B,DS014-I/B,DS014-P/B,DS014-D/B,DS014-A /C,DS014-P/C,DS014-D/A,DS014-FA,DS014-FA,DS009-N/A,DS009-I/A,DS009-A/A,DS009-P/A,DS009-A/B,DS009-I/B,DS009-I/B,DS009-D/B ,DS009-P/C,DS009-A/C,DS009-A/D,DS009-FA,DS009-FA-P,DS091-N/A,DS091-I/A,DS091-A/A,DS091-P/A,DS091-N/B,DS091-I/B,DS091-P/ B,DS091-D/B,DS091-P/C,DS091-A/C,DS091-A/D,DS091-FA,DS092-FA-P,DS041-N/A,DS041-I/A,DS041-A/A,DS041-P/A,DS041-A/B,DS041-I/B,DS041-P/B,DS041-D/B,DS041-P/C,DS041-A/C,DS041-A/D,DS041-FA,DS041-FA-P,DS072-N/A,DS072-I/A,DS072-A/A,DS072-P/A,DS072 -A/B,DS072-I/B,DS072-P/B,DS072-D/B,DS072-P/C,DS072-A/C,DS072-A/D,DS072-FA,DS104-N/A,DS104-I/A,DS104-A/A,DS104-P/A,DS104-A/B,DS104-I/B,DS104-P/B,DS104-D/B,DS104-P/C,DS104-A/C,DS104-A/D,DS104-FA,DS104-FA-P

Company Name :

Company Address :

Person responsible for making this declaration

Name, Surname : **ZhangHanzhi**

Position/Title : **Director/ Owner**

Hereby 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

Shenzhen

Zhang Hanzhi

GREATMADE TECH LIMITED 格偉迪電子科技有限公司

(Place)

March21th,2014

(Date)

(Company stamp and legal signature)

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, MCD033B-3,MC034A-3,MC034B-3, MC035A-5, 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 ,MC 052B, 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,

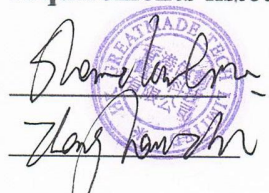
Authorized representative established within the EU (if applicable):

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__** **(Date)**

(Company stamp and legal signature)

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name : HK Greatmade Tech Limited

Manufacturer's Address : 4th, A building ,PinChuangYuan Science Technology Park ,ShuiDou New Village ,LongHua Town
Shenzhen City , Guang Dong Province , China

Product : ECG cable and Leadwire, class I

Type Designation/Trademark : ECG cable with leadwires

Product Part No. Of Manufacturer:
EC001A,EC001AD,EC001B,EC001C,EC001BI,EC001D,EC001DI,EC025A,EC025AD,EC025B,EC025BI,EC025C,EC025D,EC002AD,EC002A,EC002B,EC002BI,EC002C,EC002D,EC027A,EC027B,EC027C,EC027B,EC027A-R,EC027B-R,EC027C-R,EC027D-R,EC028A,EC008B,EC028D,EC028DI,EC030A,EC003AI,EC003A,EC004,EC004B,EC004C,EC005A,EC005B,EC005C,GE-EC022-SA,GE-EC022-CA,EC026A,EC026B,EC026C,EC029A,EC029B,EC024A/B/C/D,EC033A/B/C/D/E,EC038A/B/C/D/E/F,EC040,MR-EC0331A/B/C/D/AD/BI/BI/DI,EC006A/B/C/D,EC007A,EC007B,EC007C,EC007D/E/F/H/G,EC007A-R,EC007B-R,EC007D-R.EC00C-R,EC015A/B/C/D,EC007I,EC009A,EC009B/C/D/E/F,EC021A/B/C/D/E/F,EC010A,EC010B/C/D/E/F,EC016A/B,EC017A/B,EC011A/B/C/D,EC019A/B/C/D,EC020A/B/C/D/E/F/G/H,EC042A/B/C/D,EC041A/I,EC035A/B/C/D/E/F/G/H,EC043A/B,EC012A/B/C,EC012A/B/C/D-HP,EC012E/F,EC013A/B/C/D/E/F/G,EC018A/B/C/D,EC036A/B,EC037A/B,EC039A/B,EC014A/P ,EC023A/B/C,EC034.

Authorized representative established within the EU (if applicable):

Company Name:

Company Address :

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

Shenzhen - China
Zhang Hanzhi

(Place)
(Company stamp and legal signature)

2013.11.01
(Date)

CE Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech Limited**
Manufacturer's Address :	**6th, B Building , PinChuangYuan Science Technology, ShuiDou New Village ,LongHua town . Shenzhen City , Guang Dong Province , China**
Product :	**Spo2 Adapter cable, Class I**
Type Designation/Trademark :	**Spo2 Adapter cable**

Product Part No. Of Manufacturer: EX001,EX001-D,EX002,EX003,EX004, EX005, EX006,EX007, EX008,EX008-M,EX009,EX010,EX011,EX012,EX013,EX014,EX015,EX016,EX016-M,EX017,EX018,EX019,EX020,EX020-B,EX020-G,EX020L,EX021,EX022,EX023,EX024,EX025,EX025-M,EX025-L,EX026,EX027,EX028,EX029,EX030,EX031,EX032,EX033,EX033-X,EX034,EX035,EX036,EX037,EX038,EX039,EX040,EX041,EX042,EX043,EX044,EX045,EX046,EX047,EX048,EX049,EX050, EX051,EX052,EX053,EX0-53-M,EX054,EX055,EX056,EX057,EX057-M,EX058,EX059A,EX060,EX061,EX062,EX063,EX064,EX065,EX066,EX067,EX067-M,EX068,EX069,EX070,EX071,EX072,EX073,EX074,EX074-M,EX075,EX076,EX077,EX078,EX078,EX080-5D/5S/7S ,EX033-M

Authorized representative established within the EU (if applicable):

Company Name :	
Company Address :	

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

Shenzhen China

Zhanghanzhi

(Place)

Jan 21th, 2014

(Date)

(Company stamp and legal signature)

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 ,Baifuli Industiral Zone,shanghenglang village , LongHua town .**
	Shenzhen City , Guang Dong Province , 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,CF004LA,CF004TA , CF001B,CF002B,CF003B, CF004B, CF004LB, CF004TB, CF001C,CF002C,CF003C,CF004C, CF004LC,CF004TC,CF005,CF006.CF007A,CF007B,CF008,CF009,CF010,CF011.CF012,CF013,CF014,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,CF1105A,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

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

Shenzhen China

Zhang Hanzhi

(Place) **__Mar 19th,2018__** **(Date)**

(Company stamp and legal signature)