



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)

(Company stamp and legal signature)

Dec 24th,2012

(Date)

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
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

Page 2 of 2



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
Stefan Preiß



Page 1 of 1



Product Service





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,C
F004TB,CF001C,CF002C,CF003C,CF004C,CF004LC,CF004TC,CF001D,CF002D,CF003D,CF004D,C
F004LD,CF004TD,CF005,CF005-1.5,CF005N,CF006,CF006N,CF006-,CF007L,CF007B,CF007N,CF00
8,CF009,CF010,CF011,CF012,CF013,CF014,CF015,CF016,CF017,CF017B,CF018,CF019,CF020,CF
021,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,CF1
110A/B,CF1111A/B,CF1112A/B,CF1113A/B,CF1201A/B/C/D,CF1202A/B/C/D,CF1203A/B/C/D,CF1204
A/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,C
F1601A/B,CF1602A/B,CF1603A/B,CF1901C,CF1901I,CF1901N,BP04,BP05,BP07,BP09-MF,BP09-M
M,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 Hanzhi

(Place)

(Company stamp and legal signature)

Jan 21th, 2014

(Date)



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-DS02
4-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,DS05
1-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,DS0
51-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/DD,DS060-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



(Place)

(Company stamp and legal signature)

March21th,2014

(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 ,Baifuli Industrial 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 ,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)

(Company stamp and legal signature)

__Mar 19th, 2018__

(Date)



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,G E-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,E C043A/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)



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,EX053-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)

(Company stamp and legal signature)

Jan 21th, 2014

(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 ,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,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

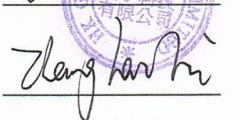
Authorized representative established within the EU (if applicable):

Company Name : Prolinx GmbH
Company Address : Brehmstr. 56,40239, Duesseldorf ,Germany

Person responsible for making this declaration

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

Mar 19th,2018

(Place)
(Company stamp and legal signature)

(Date)