



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, Pinchuang Yuan 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, AF025, 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, AF069, AF070, AF071, AF072, AF073, AF074, AF075, AF076, AF077, AF078, AF079, AF080, AF081, AF082, AF083, AF084, AF085, AF086, AF087, AF088, AF089, AF090, AF091, AF092, AF093, AF094, AF095, AF096, AF097, AF098, 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
ZhangHanzhi

(Place)

(Company stamp and legal signature)

Dec 24th, 2012

(Date)



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

Product 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)

March 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 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

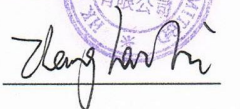
Authorized representative established within the EU (if applicable):

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)