



Compliance Report

Applicant: Shenzhen YKD Technology Co., Ltd.
Address: 2F, 8 building(separate left)XiaLingPai new industrial zone,
 Dalang community dalang street, Longhua new District, Shenzhen
 city,Guangdong Province, China

Product: ECG cable with leadwires
Type: YKD201-03, YKD201-05, YKD201-10, YKD202-03, YKD202-05

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02612
Initial Issue Date: 04 Nov 2016

Tony Chen
 General Manager (Signature)




This report is the property of NQA and should be returned to NQA upon request.



Compliance Report

Applicant: Shenzhen YKD Technology Co.,Ltd.
Address: 2F,8 building(separate left)XiaLingPai new industrial zone,
 Dalang community dalang street, Longhua new District, Shenzhen
 city,Guangdong Province, China

Product: NIBP cuff
Type: CC001A, CC001C, CC001CY, CC001D, CC002C

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02622
Initial Issue Date: 04 Nov 2016

Tony Chen
 General Manager (Signature)



This report is the property of NQA and should be returned to NQA upon request.

/

医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号

Certificate No.: YSZ20170235

产品名称: 心电导联线

Product(s): ECG Cables

规格型号

Model: CEA045A3S、CEA001A3S、CEA001A5S、CEA047A3S、CEA048A5S、CEA002A3S、CEA049A5S、CEA004A3S、CEA005A5S、CEA050A3S、CEA009A3S、CEA010A3S、CEA010I5C、CEA015A3S、CEC014A3S、CEC051A5S、CEC041A5S、CEC035I3S、CEC035I6S、CEC039A3S、CEC003A5S、CEC024A5S、CEC025A3S、CEC027A5C、CH020-10、CH018-10、CH001A10S、CH014A、CH011、CH017、CH020、CH023、CH027-7、CH030、CH028、CH031、CKA001IB、CKA002IB、CKA003IB、CKA004IB、CKA009AB、CKA022AB、CKA012AB、CKA015AB、CKA018AB、CKA019AB、CKA022AB、CKA023AB、CKB028A10S、CKB025A10B、CKB024AB、CKB005、CKB026AS、CKB027A、CKA019AB、CKA043AC、CEA092A3S、CEA108A5S、CEA086I5S、CEC053I3C、CEC061I6S、CEC064I3S、CKB033。

产品注册或备案凭证号

Registration certificate(s): 粤深械备 20160373 号

生产企业: 深圳市永康达电子科技有限公司

Manufacturer: Shenzhen YKD Technology Co., Ltd.

生产企业住所: 深圳市龙华新区大浪街道大浪社区新围浪荣路华新锐明 6 栋 6 楼

Address of manufacturer: 6F, Building 6, Huaxinruiming Industrial Area, Langrong RD, Xinwei Village, Dalang Community, Dalang Street, Longhua, Shenzhen, China.

生产许可或备案凭证号

Manufacturing License(s): 粤深食药监械生产备 20160118 号

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be manufactured and sold in China.



食品药品监督管理局
中华人民共和国深圳市食品药品监督管理局
FOOD AND DRUG ADMINISTRATION OF
SHENZHEN MUNICIPALITY
PEOPLE'S REPUBLIC OF CHINA

2017 年 / Year 06 月 / Month 12 日 / Day.

(此证明书从发证时起有效期 2 年)

(This certificate is valid for two years from the date of issuance)

医疗器械产品出口销售证明 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号

Certificate No.: YSZ20190001

产品名称: 血压袖带

Product(s): Blood Pressure Cuff

规格型号: CC001AY, CC001BY, CC001CY, CC001DY, CC001EY, CC001FY, CC002AY, CC002BY, CC002CY, CC002DY, CC002EY, CC002FY, CC001A, CC001B, CC001C, CC001D, CC001E, CC001F, CC002A, CC002B, CC002C, CC002D, CC002E, CC002F, CC005A, CC005B, CC005C, CC005D, CC005E, CC005F, CC006A, CC006B, CC006C, CC006D, CC006E, CC006F, CC007A, CC007B, CC007C, CC007D, CC007E, CC007F, CC007AF, CC007BY, CC007CY, CC007DY, CC007EY, CC007FY, CC008A, CC009A, CC010A, CC010B

Model: CC001AY, CC001BY, CC001CY, CC001DY, CC001EY, CC001FY, CC002AY, CC002BY, CC002CY, CC002DY, CC002EY, CC002FY, CC001A, CC001B, CC001C, CC001D, CC001E, CC001F, CC002A, CC002B, CC002C, CC002D, CC002E, CC002F, CC005A, CC005B, CC005C, CC005D, CC005E, CC005F, CC006A, CC006B, CC006C, CC006D, CC006E, CC006F, CC007A, CC007B, CC007C, CC007D, CC007E, CC007F, CC007AF, CC007BY, CC007CY, CC007DY, CC007EY, CC007FY, CC008A, CC009A, CC010A, CC010B

产品注册或备案凭证号

Registration certificate(s): 粤深械备 20160374 号

生产企业: 深圳市永康达电子科技有限公司

Manufacturer: Shenzhen YKD Technology Co., Ltd.

生产企业住所: 深圳市龙华新区大浪街道大浪社区新围浪荣路华新锐明 6 栋 6 楼

Address of manufacturer: 6F, Building 6, Huaxinruiming Industrial Area, Langrong RD, Xinwei Village, Dalang Community, Dalang Street, Longhua, Shenzhen, China.

生产许可或备案凭证号

Manufacturing License(s): 粤深食药监械生产备 20160118 号

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be manufactured and sold in China.

中华人民共和国深圳市食品药品监督管理局

FOOD AND DRUG ADMINISTRATION OF

SHENZHEN MUNICIPALITY

PEOPLE'S REPUBLIC OF CHINA

医疗器械出口销售
证明专用章

2019 年/ Year 01 月/ Month 07 日/ Day.



(此证明有效期与产品注册证效期相同,且最长不超过两年)

(This certificate is valid for a period equal to the life of the product registration certificate and up to two years at a maximum)