NO.2 Zhiye Road,Dalong Street
PanyuDistrict,Guangzhou,China
www.renfumed.com
Tel:+86-20-38391508
Fax:+86-20-38391505
Email: renfu@renfumed.com

Renfu Medical Products

EC - Declaration of Conformity

According to annex VII of the Council Directive 93/42/EEC (amended 2007/47/EC) concerning medical devices:

We: **Renfu Medical Products**

No.2 Zhiye Road Dalong Street Panyu District Guangzhou China

Declare that the following non-sterile medical devices under class I (according to rule 1 of annex IX of the Council Directive 93/42/EEC)

RENFU thermoplastic splint material

fulfill the basic requirements according to annex I no. 1-14 of the Council Directive 93/42/EEC (amended 2007/47/EC) Conformity assessment was performed according to Annex VII.

The above products were manufactured under the following quality management systems:

EN ISO 13485:2003

Directive 93/42/EC

The Registration number: **DE/CA05/MP-238321-0840-00**

Authorized European Representative:

Shanghai International Holding Corp. GmbH (Europe)
Dimdi No.: DE/0000040627
Add: Eiffestrasse 80, 20537 Hamburg , Germany
Tel: +49-40-2513175 Fax: +49-40-255726

Guangzhou Renfu Medical Equipment Co.,Ltd.

2015-03-11

renfu

Guangzhou Renfu Medical Equipment Co., Ltd.

Unit 1, NO.2 Zhiye Road,Dalong Street ,Panyu District,Guangzhou,China
Tel: +86-20-38391508 / 38391509 Fax: +86-20-38391505
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EC - Declaration of Conformity Annex

Subject: European Directive 93/42/EC

Worldwide there are different laws and regulations concerning medical devices. Medical devices sold in the European Community must have a CE mark. Every medical device brought onto the market needs to fulfill the requirements of the European Directive 93/42/EC and needs to be registered with the Ministry of Health. Each medical device or group of medical devices must have a CE-Declaration of Conformity. The medical devices that Renfu Medical manufactures are class 1 low risk, non-invasive products. They are in compliance with the European Directive 93/42/EC. Since it manufactures class 1 medical devices, Renfu Medical is allowed to self-certificate. It is allowed to draw up his CE-Declaration of Conformity for each medical device that it brings into the European market.

Sincerely yours

Guangzhou Renfu Medical Equipment Co., Ltd.

2016-03-11

SAO Y BẢN CHÍNH

GIÁM ĐỐC

CÔNG TY TRÁCH NHIỆM HỮU HẠN THƯƠNG MẠI ĐẦU TƯ VINH KHANG

LÝ THẾ VINH