

## CE Technical Documentation Review Report

**Applicant:** Zhangjiagang New Fellow Med Co., Ltd.  
Sanxing Wukesong Road, Jinfeng Town, Zhangjiagang  
City, Jiangsu Province 215624, China

**Report Number:** 15053585 001

**Examination intent:** Examination the completeness of the Technical  
Documentation according to the requirements of the  
Medical Devices Directive 93/42/EEC Annex VII

**Product(s):** Stretchers, Hospital Beds

**Type(s)/Model(s):** Ambulance stretcher, scoop stretcher, folding stretcher,  
stair stretcher, spine board, basket stretcher, vacuum mattress  
stretcher, stretcher trolley  
Flat bed, single-crank manual bed, double-crank manual bed, three-  
crank manual bed, examination bed  
Above model with various dimension

**Classification:** Class I, rule 1  
(according to manufacturer's declaration)

**Examination period:** 2012 Aug

**Review result:** During the examination of the provided Technical  
Documentation (No.: XFL-TCF-1, Revision 1.0, Date  
2012-07-25), no Non-compliance according to the  
requirements of the Medical Devices Directive  
93/42/EEC Annex VII was detected.

Shanghai, 10.08.2012

TÜV Rheinland (Shanghai) Co., Ltd.

*J. Ren*

Xiaoli REN  
Manager (Greater China Region)  
Medical Services





REGISTRATION NO. 04716Q10018R1S

## CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

**Zhangjiagang New Fellow Med Co., Ltd.**

Registered Address: Sanxing Wukesong Road, Jinfeng Town, Zhangjiagang  
City, Jiangsu Province, China Postcode: 215624

Manufacturing Address: Sanxing Wukesong Road, Jinfeng Town,  
Zhangjiagang City, Jiangsu Province, China

Has been assessed and conformed to the following standard(s)  
GB/T 19001-2008 idt ISO 9001:2008

The certificate is valid for the following scope:

The Design, Development, Production and Service  
of Ambulance stretcher, Hospital Bed, Stretcher Trolley,  
Folding Stretcher, Spine Board, Scoop Stretcher, Stair  
Stretcher, Basket Stretcher, Examination Couch.

Date of issue: January 08, 2016

Date of expiry: January 07, 2019

Director:

BEIJING HUA GUANG CERTIFICATION  
OF MEDICAL DEVICES CO., LTD.



MANAGEMENT SYSTEM  
CNAS C047 - Q



Note: The Certificate Information are available on the official website of Certification and Accreditation Administration of the People's Republic of China ([www.cnca.gov.cn](http://www.cnca.gov.cn)) or the Website of CMD ([www.cmd.com.cn](http://www.cmd.com.cn)).  
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