



Compliance Report

Applicant: Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd.
Address: Fuqian Economic Development Zone, Yangshe Town, Zhangjiagang City, Jiangsu Province, China.

Product: Scoop Stretcher, Stair Stretcher, Basket Stretcher, Stretcher Base, Ambulance Stretcher, Extrication Device, Neil-Robertson Stretcher, Vacuum Stretcher, Folding Stretcher, Spine Board, Patient Transfer, Emergency Blanket, Traction Splint, Resuscitator, Emergency Scissor, First-aid Kit, Air Splint, Carry Sheet, CPR Board

Type: See annex for details

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. 02347

Initial Issue Date: 03 Jun 2015

Tony Chen

General Manager (Signature)



Annex to Report (No. 02347)

Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd.

Product Name	Type
Scoop Stretcher	YXH-4A, YXH-4B, YXH-4C, YXH-4D
Stair Stretcher	YXH-5A, YXH-5B, YXH-5C, YXH-5D, YXH-5E, YXH-5F
Basket Stretcher	YXH-6A, YXH-6B, YXH-6C, YXH-6D
Stretcher Base	YXH-7A, YXH-7B, YXH-7C
Ambulance Stretcher	YXH-2A, YXH-2B, YXH-2C, YXH-3A, YXH-3A2, YXH-A3, YXH-3A5, YXH-3B, YXH-3B2, YXH-3B3, YXH-3C, YXH-3D, YXH-3D2, YXH-3E, YXH-3F, YXH-3G, YXH-2L, YXH-3L
Extrication Device	YXH-7H
Neil-Robertson Stretcher	YXH-7N
Vacuum Stretcher	YXH-7D, YXH-7E
Folding Stretcher	YXH-1A1, YXH-1A2, YXH-1A3, YXH-1A5, YXH-1A6, YXH-1B1, YXH-1B2, YXH-1B3, YXH-1C, YXH-1D, YXH-1DL, YXH-1E, YXH-1EF, YXH-1EL, YXH-1F1, YXH-1F1B, YXH-1F2, YXH-1F3, YXH-1F4, YXH-1F4A, YXH-1G, YXH-1H, YXH-1L, YXH-1M, YXH-1N(A), YXH-1N(B)
Spine Board,	YXH-1A6A, YXH-1A6B, YXH-1A6C, YXH-1A6D, YXH-1A6E, YXH-1A6F, YXH-1A6G, YXH-1A6K, YXH-1A6M, YXH-1A6N, YXH-1A6H, YXH-1A6L
Patient Transfer	YXH-8A
Emergency Blanket	XH-18
Traction Splint	YXH-8B
Resuscitator	XH-KB04, XH-KB05, XH-KB06, XH-KB07, XH-KB09, XH-KB10
Emergency Scissor	XH-21
First-aid Kit	XH-07C, XH-07Z, XH-08007, XH-CZ2, XHE-1, XHE-2, XHE-3, XHE-4, XHE-5
Air Splint	YXH-9A
Carry Sheet	YXH-4E
CPR Board	YXH-1A6H

This annex is only valid if attached to the report mentioned above.