



Compliance Report

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

Product: HESTIA-MULTI-LEVEL AUTOMATIC LOADING
AMBULANCE STRETCHER WITH FOLDABLE LEGS WAND
WHEELS YXH-3D, One-piece Basket Stretcher, Two-piece Basket
Stretcher, HERMES I-METALLIC BASKET STRETCHER
YXH-6C, Folding Stretcher, YXH-4D HEPHAESTUS II-SCOOP
WITH 4 BLADES, SCOOP STRETCHER YXH-4B, Stair Stretcher,
Splint, Philadelphia Collar, Cervical Collar, Adjustable Collar, Three
Fold Screen, 2 Hooks IV Pole, 4 Hooks IV Pole, Head Immobilizer

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. 02348

Initial Issue Date: 03 Jun 2015

Tony Chen

General Manager (Signature)

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



Annex to Report (No. 02348)

Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd.

Product Name	Type
HESTIA- MULTI-LEVEL AUTOMATIC LOADING AMBULANCE STRETCHER WITH FOLDABLE LEGS WAND WHEELS YXH-3D	YXH-3D
One-piece Basket Stretcher	YXH-6A
Two-piece Basket Stretcher	YXH-6B
HERMES I-METALLIC BASKET STRETCHER YXH-6C	YXH-6C
Folding Stretcher	Venus I stretcher, Venus II stretcher
YXH-4D HEPHAESTUS II- SCOOP WITH 4 BLADES	YXH-4D
SCOOP STRETCHER YXH-4B	YXH-4B
Stair Stretcher	YXH-5E
Splint	S/M/L/XL
Philadelphia Collar	XH-17B
Cervical Collar	XH-17
Adjustable Collar	XH-19
Three Fold Screen	YH-4
2 Hooks IV Pole	XH-512 ,XH-509
4 Hooks IV Pole	XH-510 ,XH-511
Head Immobilizer	XH-16

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