

File No: CE-TCF-001



EC Declaration of Conformity



Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Manufacturer

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

EC Representative

Name: SUNGO CRETIFICATION COMPANY LIMITED
Address: RM101, MAPLE HOUSE, 118 HIGH STREET, PURLEY, LONDON, ENGLAND

Product

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

Type: See Annex of details

Classification: I

Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2012
EN 1041:2008
EN 1865-1:2010

Signature: 

Date: 2015-05-06



Annex

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

