

CE Documentation Review



No. 0L181011.JRMTO42

Holder: JIANGSU RIXIN MEDICAL EQUIPMENT Co., Ltd.

No. 427 Yangjin Road Jinfeng Town Zhangjiagang City Jiangsu Province China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Stretcher for Ambulance Car, Foldaway Stretcher, Scoop Stretcher, Stair Stretcher, PE Stretcher, Basket Stretcher, Vacuum Mattress Stretcher, Carry Sheet, Emergency Bed, Cervical Collar, Head Immobilize, I.V. Stand, Body Splint, Traction Leg Splint, Stretcher Base, Safety Belts, Examination Couch

Model(s): (see the following annex I)

Classification: Class I (accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Technical File identified with the no. CE/MDD-2018/(A0) dated 2018.09. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

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Annex I

No. 0L181011.JRMTO42

Stretcher For Ambulance Car	YDC-2A, YDC-2B, YDC-2C, YDC-3A, YDC-3A02, YDC-3A03, YDC-3B, YDC-3B02, YDC-3B03, YDC-3B04, YDC-3B05, YDC-3C, YDC-3C02, YDC-3D, YDC-3D02, YDC-3D03, YDC-3D04, YDC-3E, YDC-3E02, R-EHS02, R-EHS-03, YDC-3F, YDC-3G, YDC-3G02, YDC-3H, YDC-3H02, YDC-3H03, YDC-3K, YDC-3K04, YDC-3Y02, CT-01, CT-02
Foldaway Stretcher	YDC-1A1, YDC-1A3, YDC-1A4, YDC-1A4H, YDC-1A5, YDC-1A6, YDC-1A7, YDC-1A9, YDC-1A10, YDC-1A11, YDC-1A12, YDC-1A13, YDC-1A16, YDC-1A17, YDC-1F1, YDC-1F2, YDC-1F3
Scoop Stretcher	YDC-4A, YDC-4A02, YDC-4B, YDC-4B02, YDC-4C, YDC-4D
Stair Stretcher	YDC-5L, YDC-5L01, YDC-5L02, YDC-5G, YDC-5M, YDC-5P, YDC-5T1, YDC-5T2, YDC-5R
PE Stretcher	YDC-7A1, YDC-7A3, YDC-7A4, YDC-7B1, YDC-7B2, YDC-7C1, YDC-7D1, YDC-7E
Basket Stretcher	YDC-8A1, YDC-8A6, YDC-8B1, YDC-8B6
Vacuum Mattress Stretcher	YDC-6A1, YDC-6A4
Carry Sheet	CST-01, CST-05
Emergency Bed	YQC-2L, YDC-2L02, YQC-2R, YQC-3L, YQC-3M, YQC-3M1, YQC-3S, YQC-3T, YQC-3TX, YQC-3W, YQC-2RR, YQC-3LL, YQC-4L, RL-M20
Cervical Collar	CC-01 (adult, child), CC-02, CC-03, CC-04
Head Immobilize	HD-01, HD-03
I.V. Stand	RT-1/2/3/4/5/6/7/8
Body Splint	BS-01 (Adult, Child), AS-01, AS-02, AS-03, AS-04, CB-01, AM-01, FS-121(S/L/M), FS-127(S/L/M), FS-128(S/L/M), FS-129(S/L/M), FS-130(S/L/M), PS-01, PM-01
Traction Leg Splint	TS-01, TS-02
Stretcher Base	PF-01, PF-02, PF-03, PF-04, PF-05, PF-06
Safety Belts	B2, B3, B4, B8, B9, B10, B11, B12
Examination Couch	ET-01, ET-02, ET-03