



Compliance Report

Applicant: JiangSu Senolo Medical Technology Co., Ltd.
Address: No.88, 4th Road, Private Venture Park, Jianhu County, Jiangsu
224700 China

Product: Orthopedic Splint, Ultrasound Gel, Electric Cast Saw, Orthopedic Casting Tape, Plaster Bandage, Self-adhesive Bandage, Soft Cast, Stockinette, Gauze Bandage, Tourniquet, Cast Padding, Elastic Bandage, Foetal Belt, Hemostatic Paster, Kinesiology Tape

Type: See annex for details

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. **02448**

Initial Issue Date: **16 Dec 2015**

Reissue Date: **7 Feb 2018**

A blue ink signature that reads 'Tony Chen' in a cursive script. The signature is positioned over a faint, circular official seal of NQA.

Tony Chen

General Manager (Signature)

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



Annex to Report (No. 02448)

JiangSu Senolo Medical Technology Co., Ltd.

Product Name	Type
Orthopedic Splint	XB212, XB224, XB312, XB320, XB324, XB328, XB336, XB416, XB420, XB428, XB430, XB436, XB528, XB530, XB545, XB546, XB548, XB636, XB646, XB648, XB5180, XB630, XB536
Ultrasound Gel	10g, 12g, 15g, 18g, 20g, 22g, 250ml, 1l, 2l, 5l
Electric Cast Saw	XC-DSII
Orthopedic Casting Tape	XD1, XD2, XD3, XD4, XD5, XD6
Plaster Bandage	5cmx2.7m, 7.5cmx2.7m, 10cmx2.7m, 12.5cmx2.7m, 15cmx2.7m, 20cmx2.7m
Self-adhesive Bandage	2.5cmx4.5m, 5cmx4.5m, 7.5cmx4.5m, 10cmx4.5m, 15cmx4.5m
Soft Cast	XD1, XD2, XD3, XD4, XD5, XD6
Stockinette	According to the customer request
Gauze Bandage	According to the customer request
Tourniquet	According to the customer request
Cast Padding	5cmx2.7m, 7.5cmx2.7m, 10cmx2.7m, 12.5cmx2.7m, 15cmx2.7m, 20cmx2.7m
Elastic Bandage	5cmx4.5m, 7.5cmx4.5m, 10cmx4.5m, 15cmx4.5m
Foetal Belt	4.5cmx130cm, 6cmx130cm
Hemostatic Paster	27mmx16mmx8.5mm, 27mmx16mmx5.5mm, 27mmx27mm, 14mmx14mm
Kinesiology Tape	According to the customer request

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