

EC Declaration of Conformity



Manufacturer:

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.

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whose single Authorized Representative:

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We, the manufacturer, herewith declare that the products

Sealing Machine – SELINA, FOSEAL

meet the provisions of Directive 93/42/EEC and 2007/47/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex V Quality Assurance Medical Devices of Directive 93/42/EEC.

Applied harmonized standards or national standards:

EN60601-1:2006+A1:2013+AC:2012+A12:2014

EN60601-1-2:2015

following the procedure relating to the EC Declaration of Conformity set out in Annex V Production Quality Assurance Medical Devices of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.

2023/03/31 – Ningbo, China
Place, date



Name: Xie Diyan

Position: Vice General Manager

Signature:

Legally binding signature, Function