

EC Declaration of Conformity



Manufacturer:

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.

No.25, Lane 300, Jinshan Road, Jiangbei District,

Ningbo 315032, China

Tel: 0086 574 83022668

Fax: 0086 574 87637357

whose single Authorized Representative:

Caretechion GmbH

Niederrheinstr. 71, 40474 Duesseldorf, Germany

Tel: +49 211 3003 6618

Fax: +49 211 3003 6619

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.

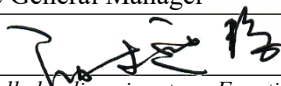
2023/03/31 – Ningbo, China
Place, date



Name: Xie Diyan

Position: Vice General Manager

Signature:


Legally binding signature, Function

EC Declaration of Conformity



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We, the manufacturer, herewith declare that the products

Steam Sterilizer – TANZO E, Z-CLAVE IIB, ARIES

UMDNS-Code: 13746; GMDN-Code: 38671

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

The medical device has been assigned to class IIB according to rule 15 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 II (excluding Section 4) of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Product GmbH -

Tillystraße 2-90431 Nürnberg

Identification Number: 0197

Certificate No.: HD 2058015-1

following the procedure relating to the EC Declaration of Conformity set out in Annex II (excluding Section 4) 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.

2024/03/31 – Ningbo, China

Place, date



Name: Xie Diyan

Position: Vice General Manager

Signature:

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.

No.25, Lane 300, Jinshan Road, Jiangbei District,
Ningbo 315032, China

Tel: 0086 574 83022668

Fax: 0086 574 87637357

whose single Authorized Representative:

DTF TECHNOLOGY srl

via Gressoney 9, 20137 Milano, Italy

tel: +39.02.84893641

fax: +39.02.84718594

We, the manufacturer, herewith declare that the products

Steam Sterilizer - TANZO E series

UMDNS-Code: 13746; GMDN-Code: 38671

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

The medical device has been assigned to class IIb according to rule 15 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 II (excluding Section 4) of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Product GmbH -
Tillystraße 2-90431 Nürnberg
Identification Number: 0197**

Certificate No.: HD 60108780 0001

Issue date: 2016/03/28

Expiry date: 2021/03/16

following the procedure relating to the EC Declaration of Conformity set out in Annex II (excluding Section 4) 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.

2016/03/28 – Ningbo, China

Place, date



Name: Liu Bin

Position: Director of Operations

Signature:

Legally binding signature, Function

