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

CE

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

宁波江北华鑫医疗器械有限公司

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
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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

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

CE 0197

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

宁波北仑鑫医疗器械有限公司

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

CE **0197**

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