EC Declaration of Conformity

Manufacturer:
NINGBO HAISHU YESON MEDICAL DEVICE CO., LTD
NO.1 Huanzhen Dadao, Hengjie Town, Haishu, Ningbo,Zhejiang, China
Tel:+86-574-88425999
Fax:+86-574-88281777

whose single Authorized Representative:
MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
Tel: +49(0)8961306837
Email:info@medpath.pro

We, the manufacturer, herewith declare that the products
Steam sterilizer Model: YS-8L,YS-12L,YS-18L,YS-22L;
YS-03L-E,YS-03L-E1,YS-8L-E,YS-12L-E, YS-18L-E, YS-22L-E;

GMDN-CODE: 38671

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

The medical device has been assigned to class IIb according to 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 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 Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.:HD 2074786-1
Issue date: 2021-04-01
Expiry date: 2024-05-26
Notified Body Confirmation letter reference: 326013728

following the procedure relating to the EC Declaration of Conformity set out in Annex Ⅱ of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.
We declare that we meet the conditions to continue placing the above items on the market and putting into service until the date of Dec 31 th,2028.

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

NINGBO HAISHU YESON MEDICAL DEVICE CO., LTD

NO.1 Huanzhen Dadao, Hengjie Town, Haishu, Ningbo,Zhejiang, China

General Manager:

John Chen

Oct. 11th,2024

Ningbo Haishu Yeson Medical Device Co., Ltd