

## EC Declaration of Conformity

**Manufacturer:**

Zhejiang Fomos Medical Technology Co., Ltd.  
Floor 3, Block 21, No.205, Guangyuan Road, Jiangbei  
District, Ningbo City, Zhejiang Province  
TEL: 86-574-87118655  
FAX: 86-574-87118655

**whose single Authorized Representative:**

BLUMEN 97 LTD.  
BULGARIA SOFIA 1231,  
NADEZHDA 4  
Tel.: +359 2 920 37 20  
Attn. Mr. Chudomir Vasilev Hristov

We, the manufacturer, herewith declare that the products

**Steam Sterilizer – Foster-8L, Foster-12L, Foster-17L, Foster-22L, Foster Plus-17L, Foster Plus-22L**

**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

**Polskie Centrum Badań i Certyfikacji S.A.-**

23A Kłobucka Street, 02-699 Warsaw

Identification Number: 1434

Certificate No.: 1434-MDD-240/2020

Issue date: 03.06.2020

Expiry date: 27.05.2024

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

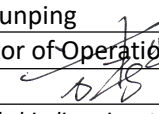
**Zhejiang Fomos Medical Technology Co., Ltd.**

3<sup>rd</sup>/June/2020 – Ningbo, China

*Place, date*

Name: Fang Chunping

Position: Director of Operations

Signature: 

*Legally binding signature, Function*