

## Declaration of conformity

a. Manufacturer

Manufacturer name: Jiangyin Fanmei Medical Device Co., Ltd.  
Manufacturer address: No.19 Yishan Rd, Lingang Street, 214400 Jiangyin, People' s Republic of China  
Tel: 0086-510-86688750      Fax: 0086-510-86688750      E-mail: info@fmsyringe.com

b. EC-representative

EC-representative name: ZOUSTECH S.L.  
EC-representative address: Pso. Castellana, 141 - Planta 19, 28046 - Madrid, Spain  
Tel: +34694426446      Fax: +34917915466      E-mail: [legal@zoustech.eu](mailto:legal@zoustech.eu)

c. Product name: Syringe for Insulin

d. UMDNS Code of product: 13941

e. Classification of product: MDD 93/42/EEC Class IIa (Rule 6)

f. Conformity assessment route: MDD 93/42/EEC Annex V3

g. We declare:

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the promises of the manufacturer. Our company is exclusively responsible for this Declaration of Conformity.

h. We follow the applicable directives include:

General applicable directives:  
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC


i. Notified body

Notified Body name: TUV SUD Product Service GmbH  
Notified Body address: Ridlerstr65 Munich 80339, Germany  
Identification number: 0123

Certificate No.: G20945580005 Rev:01

Valid until 2024-05-26

CE-marking starting batch or date: 2016-10-8

Signature of issuing person: 

Name: Weijun Shao

Title: General Manager

Location: Jiangyin, China





江阴市泛美医疗器械有限公司  
JIANGYIN FANMEI MEDICAL DEVICE CO.,LTD  
TEL:86-510-86688750 FAX:86-510-86688750

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c. Product name: Sterile Syringe for Single Use (with Needle)

d. UMDNS Code of product: 13929

e. Classification of product: MDD 93/42/EEC Class IIa (Rule 6)

f. Conformity assessment route: MDD 93/42/EEC Annex V.3

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Certificate No.: G2 094558 0005 Rev.01

Valid until 2024-05-26

CE-marking starting batch or date:2016-10-18



Signature of issuing person:

Name: Weijun Shao

Title: General Manager

Location: Jiangyin, China

