



GUANGZHOU FAME MEDICAL CO., LTD.

First Floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain Bonded Area,
Shilou Town, Panyu District, 511440 Guangzhou, People's Republic of China.
Tel: 0086-20-31062968 Fax:0086-20-31062978

Declaration of Conformity

MANUFACTURER:

Guangzhou Fame Medical Co., Ltd.

Address: Second floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain Bonded Area, Shilou Town, Panyu District, 511440 Guangzhou, People's Republic of China

AUTHORIZED REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, GERMANY

MEDICAL DEVICE:

Model Name: Pessaries

Type: Ring, RingWS, RingWK, RingWKS, Gellhorn, DishWS, iDish, Dish, Cup, CupWS, Donut, Shaatz, Cube, Pessary Fitting Set

Size: 25mm, 29mm, 33mm, 37mm, 38mm, 41mm, 45mm, 50mm, 51mm, 55mm, 56mm, 57mm, 60mm, 63mm, 64mm, 65mm, 70mm, 75mm, 76mm, 80mm, 83mm, 89mm, 95mm, 102mm

Classification: IIa (Rule 5 of Annex IX, MDD 93/42/EEC amended 2007)

UMDNS code: 13004

Conformity Assessment Procedure: Annex V

We herewith declare in our own responsibility that the above-mentioned product(s) meet(s) the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer (head of Quality department).

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC.

We are exclusively responsible for the DoC

Applicable standard(s):

ENISO13485:2016/ ENISO14971:2012/ EN ISO 11135:2014/ EN980:2008/ ENISO15223-1:2016/ EN 1041:2008+A1:2013/ ENISO11737-1:2006/AC:2009/ EN556-1:2001/AC:2006/ ENISO11737-2:2009/ ENISO11607-1:2009 /ENISO11607-2:2006/ ENISO10993-1:2018/ ENISO10993-5:2009/ ISO10993-10:2010/ENISO10993-7:2008/AC:2009/ ENISO11138-1:2017/ ENISO11138-2:2009/

Notified Body: TÜV SÜD Product Service GmbH

Address: Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany.

Identification No.: 0123

EC Certificate(s): No. G2 003095 0003 Rev.01

EC certificate(s) valid until: 2024-05-26

In accordance with EU 2023/607, the validity of MDD EC certificate is extended to 31 December 2028. Our confirmation letter of the extension is as below:

Confirmation No.: CL 003095 0006 Rev.00

EC Certificate(s) validity extended to: 2028-12-31

Person keeping the technical documentation: Kang binbin (Management Representative)

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District, 511440 Guangzhou, People's Republic of China

广州市汇铭生物科技有限公司

Cao shuhua

GUANGZHOU FAME MEDICAL CO.,LTD.
General Manager

Guangzhou, China. 15th/April/2025

(Place and date of issue of this certificate)*

(Signature and title of authorized person)*