EC Declaration of Conformity

EC Declaration of Conformity

Manufacturer:

Zhejiang Geyi Medical Instrument Co.,Ltd
No. 190, Chutian Road, Xixing Street,Binjiang Zone, Hangzhou, Zhejiang Province 310051, P.R. China

whose single Authorized Representative:

Lotus Global Co., Ltd
15 Alexandra Road London NW8 0DP United Kingdom
Tel: +0044-20-75868010

We, the manufacturer, herewith declare that the products

Disposable Circular Staplers

UMDNS-Code: **16-224**; *GMDN-Code/Preferred Terms:* **45183**

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 (*or* Annex V) 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 600811690001
Issue date: 2012-12-14
Expiry date: 2017-1213

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

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

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

Company: Zhejiang Geyi Medical Instruments Co.,Ltd
Address: No. 190, Chutian Road, Xixing Street,Binjiang Zone, Hangzhou, Zhejiang Province 310051, P.R. China

Place, date

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

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No. 190, Chutian Road, Xixing Street,Binjiang Zone, Hangzhou, Zhejiang Province 310051, P.R. China

whose single Authorized Representative:

Lotus Global Co., Ltd
15 Alexandra Road London NW8 0DP United Kingdom
Tel: +0044-20-75868010

We, the manufacturer, herewith declare that the products
Disposable Circular Stapler for Hemorrhoids

UMDNS-Code: **16-224**; *GMDN-Code/Preferred Terms:* **46737**

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

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No. 190, Chutian Road, Xixing Street,Binjiang Zone, Hangzhou, Zhejiang Province 310051, P.R. China

whose single Authorized Representative:

Lotus Global Co., Ltd
15 Alexandra Road London NW8 0DP United Kingdom
Tel: +0044-20-75868010

We, the manufacturer, herewith declare that the products

Disposable Linear Staplers

UMDNS-Code: **16-224**; *GMDN-Code/Preferred Terms:* **46335**

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

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Manufacturer:

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No. 190, Chutian Road, Xixing Street,Binjiang Zone, Hangzhou, Zhejiang Province 310051, P.R. China

whose single Authorized Representative:

Lotus Global Co., Ltd
15 Alexandra Road London NW8 0DP United Kingdom
Tel: +0044-20-75868010

We, the manufacturer, herewith declare that the products

Disposable Linear Cutter Staplers

UMDNS-Code: **16-224**; *GMDN-Code/Preferred Terms:* **45183**

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

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Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

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Place, date *Legally binding signature, Function*

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Zhejiang Geyi Medical Instrument Co.,Ltd
No. 190, Chutian Road, Xixing Street,Binjiang Zone, Hangzhou, Zhejiang Province 310051, P.R. China

whose single Authorized Representative:

Lotus Global Co., Ltd
15 Alexandra Road London NW8 0DP United Kingdom
Tel: +0044-20-75868010

We, the manufacturer, herewith declare that the products
Disposable Trocars

UMDNS-Code: **16-224**; *GMDN-Code/Preferred Terms:*

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

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

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whose single Authorized Representative:

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15 Alexandra Road London NW8 0DP United Kingdom
Tel: +0044-20-75868010

We, the manufacturer, herewith declare that the products

Disposable Suction Irrigation Sets

UMDNS-Code: **16-224**; *GMDN-Code/Preferred Terms:*

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

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

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whose single Authorized Representative:

Lotus Global Co., Ltd
15 Alexandra Road London NW8 0DP United Kingdom
Tel: +0044-20-75868010

We, the manufacturer, herewith declare that the products

Disposable Linear Cutter For Endoscope Use

UMDNS-Code: **16-224**; *GMDN-Code/Preferred Terms:* **45183**

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

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