

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistirct,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Endoscopic Biopsy Forceps

UMDNS-Code: 16268

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

The product concerned has been designed and manufactured under a quality management system according to 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company: Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistirct,Changzhou, Jiangsu

Changzhou 2020.02.10
Place, date

Anne Li
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistirct,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Cytology Brushes

UMDNS-Code: 15018

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

The product concerned has been designed and manufactured under a quality management system according to 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistirct,Changzhou,
Jiangsu

Changzhou 2020.02.10
Place, date

Anne Li
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistict,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Endoscopic Retrievers

UMDNS-Code: 15628

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

The product concerned has been designed and manufactured under a quality management system according to 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistict,Changzhou, Jiangsu

Changzhou 2020.02.10

Place, date

Anne Li

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistict,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Endoscopic Injection
Needles

UMDNS-Code: 20212

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

The product concerned has been designed and manufactured under a quality management
system according to 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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
Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistict,Changzhou,
Jiangsu

Changzhou 2020.02.10
Place, date

Anne Li
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistirct,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Spray Catheters

UMDNS-Code: 16529

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

The product concerned has been designed and manufactured under a quality management system according to 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistirct,Changzhou, Jiangsu

Changzhou 2020.02.10
Place, date

Anne Li
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistirct,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Laparoscopic Trocars

UMDNS-Code: 14155

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

The product concerned has been designed and manufactured under a quality management system according to 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistirct,Changzhou, Jiangsu

Changzhou 2020.02.10
Place, date

Anne Li
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistrict,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Anorectal Ligation
Devices

UMDNS-Code: 12335

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

The product concerned has been designed and manufactured under a quality management
system according to 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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
Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistrict,Changzhou,
Jiangsu

Changzhou 2020.02.10

Place, date

Anne Li

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistirct,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Skin Staplers

UMDNS-Code: 20324

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

The product concerned has been designed and manufactured under a quality management system according to 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistirct,Changzhou, Jiangsu

Changzhou 2020.02.10
Place, date

Anne Li
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistirct,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Bite Blocks

UMDNS-Code: 10405

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

The medical device has been assigned to class I* 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 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistirct,Changzhou, Jiangsu

Changzhou 2020.02.10
Place, date

Anne Li
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistirct,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Disposable Bougie Dilators

UMDNS-Code: 11597

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

The medical device has been assigned to class I* 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 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistirct,Changzhou, Jiangsu

Changzhou 2020.02.10
Place, date

Anneli
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Jiangsu Grit Medical Technology Co.,Ltd

Address:

B4,3rd Floor,Hutang Science Technology
Industrial Park,WujinDistirct,Changzhou,
Jiangsu

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH
(Europe)

Address:

Eiffestrasse 80,20537 Hamburg,Germany

We, the manufacturer, here with declare that the products: Cleaning Brush for Endoscopes

UMDNS-Code: 10500

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

The medical device has been assigned to class I* 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 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.: 15096360 002

Issue date: 2020-02-03

Expiry date: 2024-04-14

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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 Company:Jiangsu Grit Medical Technology Co.,Ltd

Address: B4,3rd Floor,Hutang Science Technology Industrial Park,WujinDistirct,Changzhou, Jiangsu

Changzhou 2020.02.10
Place, date

Anne Li
Legally binding signature, Function