EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60114910 0001

Report No.: 16801992 006

Manufacturer:
Shangxian Minimal Invasive
Inc.
1st Floor,Block B2-2
China medicine innovation park
Mulan road,Hi-tech development zone
Benxi
117004 Liaoning
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60110060 0001

Expiry Date: 2020-07-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-01-05

Date: 2017-01-05

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60114910 0001
Report No.: 16801992 006

Manufacturer:
Shangxian Minimal Invasive Inc.
1st Floor,Block B2-2
China medicine innovation park
Mulan road,Hi-tech development zone
Benxi
117004 Liaoning
China

Products:

- Electrogastrographs
- Disposable Nebulizer Masks
- Disposable Biopsy Forceps
- Disposable Endoscopic Distal Attachments
- Disposable Hemostasis Clips and Delivery Systems
- Capsule Endoscopy Systems
- Disposable Hemostasis Clips
- Disposable Grasping Forceps
- Disposable Injection Needles
- Electronic Stethoscopes

Aspects of manufacture concerned securing and maintaining sterile conditions:

- Disposable Guide Wires

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

X. Ren

Date: 2017-01-05

EC Declaration of Conformity

Supplier: Shanghai Tuoxiao Intelligent Technology Co., Ltd.

Manufacturer: Shangxian Minimal Invasive Inc.

Manufacturer Address: 1 st Floor, Block B2-2 China medicine innovation park, Mulan road, Hi-tech development zone, Benxi, 117004 Liaoning, China

Product name: Electronic Stethoscopes

Model: G-100

Classification (MDD, Annex IX): Class IIb, Rule 10

Conformity Assessment Route: Directive 93/42/EEC Annex II, excluding Section 4

We herewith declare that the above-mentioned products meet the transposition into the national law, the provisions of the following EC Council Directive and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

Council device 93/42/EEC on medical Directives:

Medical Device Directive: Council directive 93/42/EEC of 14 June 1993 concerning Medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body:

TUV SUD Product Service GmbH

EC Certificate(s): HD 60114910 0001

Expire date of the Certificate: 2020-07-27

Start of CE marking: 2017-01-05