TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60103475 0001

Report No.: 15085363 001

Manufacturer:
Taizhou Kangjian Medical
Equipments Co., Ltd.
The Machine Electricity Zone
(Hang Ni Kan) of Yuhuan County
Zhejiang Province 317600
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60090434 0001

Expiry Date: 2020-09-27

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Effective Date: 2015-09-28

Date: 2015-09-28

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.

Digitally signed by Potînga Stela
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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60103475 0001
Report No.: 15085363 001

Manufacturer: Taizhou Kangjian Medical Equipments Co., Ltd.
The Machine Electricity Zone
(Hang Ni Kan) of Yuhuan County
Zhejiang Province 317600
China

Products:

- Disposable Cervical Brushes
- Disposable Cervical Spatulas
- Disposable Cervical Cell Sampling Spoons
- Disposable Gynecological Sets

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile Vaginal Speculums for Single Use
- Disposable Anoscopes
- Disposable Nasal Speculums
- Disposable Tongue Depressors

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

X. Ren

Date: 2015-09-28