EC Certificate

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

Registration No.: DD 60144541 0001

Report No.: 15096377 002

Manufacturer: Jiangsu HanHeng Medical Technology Co., Ltd.
16-B4, #1 North Qingyang Road,
Tianning District,
Changzhou,
213017 Jiangsu
P.R. China

Products: Medical Devices

(see attachment for products included)

Expiry Date: 2024-05-27

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.

Effective Date: 2019-11-25

Date: 2019-11-25

Notified Body

Digitally signed by Ionaşcu Andrei
Date: 2023.09.15 20:27:31 EEST
Reason: MoldSign Signature
Location: Moldova

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60144541 0001
Report No.: 15096377 002

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16-B4, #1 North Qingyang Road,
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Aspects of manufacture concerned with securing and maintaining sterile conditions: Gynecological Kits (including Disposable Vaginal Dilators, Disposable Cervical Samplers, Disposable Medical Drapes, Disposable Examination Gloves), Disposable Sampling Swabs, Disposable Cervical Samplers, Disposable Sampling Brushes, Umbilical Cord Clamps

Notified Body

Date: 2019-11-25

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
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Zertifizierungsstelle