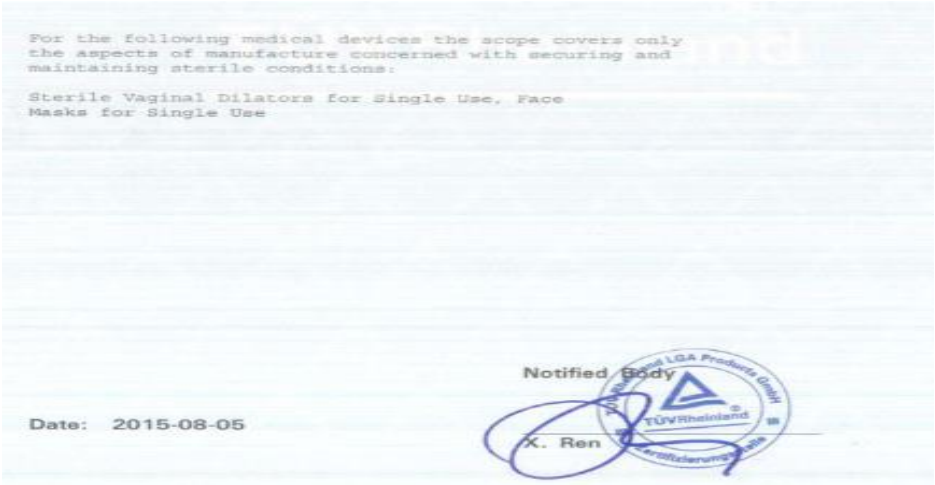
CE 证书说明（含口罩）

April 25, 2020

1. Validation 有效期: 2015/8/5-2020/8/4
   Registration No. 注册号：HD 60103576 0001
   Report No.报告号：15084181 001


For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

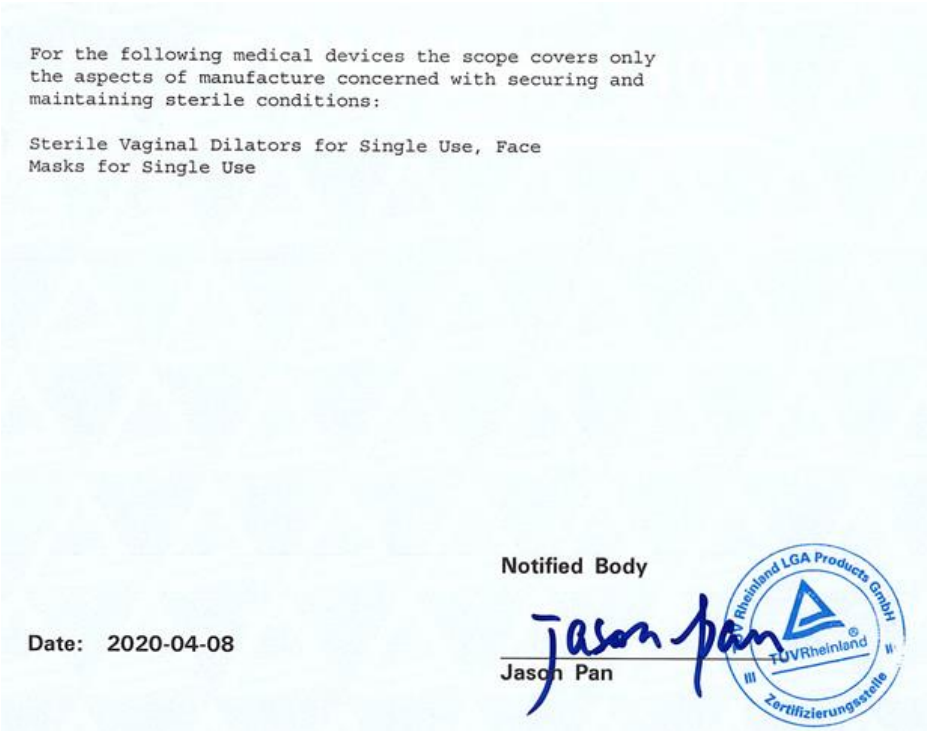
Sterile Vaginal Dilators for Single Use, Face Masks for Single Use

Notified Body

Date: 2015-08-05

X. Ren

2. Update 更新：2020/4/8-2024/5/26
   Registration No. 注册号：HD 60147620 0001
   Report No. 报告号：15084181 009


For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Vaginal Dilators for Single Use, Face Masks for Single Use

Notified Body

Date: 2020-04-08

Jason Pan

Updated CE 更新证书

TÜVRheinland®

EC Certificate

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

Registration No.: HD 60147620 0001

Report No.: 15084181 009

Manufacturer: Jiangxi Yikang Medical Instrument
Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60103576 0001

Expiry Date: 2024-05-26

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: 2020-04-08

Date: 2020-04-08

Notified Body

Jason Pan

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.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147620 0001
Report No.: 15084181 009

Manufacturer:
Jiangxi Yikang Medical Instrument Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
P.R. China

Products:
Sterile Urethral Catheters for Single Use, Intravenous Catheters for Single Use, Sterile Tracheal Tubes for Single Use, Sterile Tracheostomy Tubes for Single Use, Sterile Intubating Stylets for Single Use, Oxygen Masks, Nebulizers, Sterile Oropharyngeal Airways for Single Use, Sterile Nasopharyngeal Airways for Single Use, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Sterile Latex T-Drainage Tubes for Single Use, Sterile Pezzer Latex Catheters for Single Use, Sterile PVC Catheters for Single Use, Sterile Suction Catheters for Single Use, Sterile Stomach Tubes for Single Use, Sterile Feeding Tubes for Single Use, Sterile Blood Taking Sets for Single Use, Sterile Retraction Self Destruction Syringes for Single Use, Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Intravenous Needles for Single Use, Sterile Transfusion Sets for Single Use, Sterile Burette Type Infusion Sets for Single Use, Bag-type Infusion Sets for Single Use with Needles, Infusion Sets with Precision Filters for Single Use with Needles;

Notified Body

Date: 2020-04-08

Jason Pan

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147620 0001
Report No.: 15084181 009

Manufacturer: Jiangxi Yikang Medical Instrument Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
P.R. China

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Vaginal Dilators for Single Use, Face Masks for Single Use

Notified Body

Date: 2020-04-08

Jason Pan

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Previous CE 原始证书

TÜVRheinland®

EC Certificate

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

Registration No.: HD 60103576 0001

Report No.: 15084181 001

Manufacturer: Jiangxi Yikang Medical Instrument
Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60095592 0001

Expiry Date: 2020-08-04

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: 2015-08-05

Date: 2015-08-05

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: HD 60103576 0001
Report No.: 15084181 001

Manufacturer: Jiangxi Yikang Medical Instrument
Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
China

Products:
Sterile Urethral Catheters for Single Use, Intravenous Catheters for Single Use, Sterile Tracheal Tubes for Single Use, Sterile Tracheostomy Tubes for Single Use, Sterile Intubating Stylets for Single Use, Oxygen Masks, Nebulizers, Sterile Oropharyngeal Airways for Single Use, Sterile Nasopharyngeal Airways for Single Use, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Sterile Latex T-Drainage Tubes for Single Use, Sterile Pezzer Latex Catheters for Single Use, Sterile PVC Catheters for Single Use, Sterile Suction Catheters for Single Use, Sterile Stomach Tubes for Single Use, Sterile Feeding Tubes for Single Use, Sterile Blood Taking Sets for Single Use, Sterile Retraction Self Destruction Syringes for Single Use, Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Intravenous Needles for Single Use, Sterile Transfusion Sets for Single Use, Sterile Burette Type Infusion Sets for Single Use, Bag-type Infusion Sets for Single Use with Needles, Infusion Sets with Precision Filters for Single Use with Needles;

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2015-08-05

X. Ren

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: HD 60103576 0001
Report No.: 15084181 001

Manufacturer: Jiangxi Yikang Medical Instrument
Group Co., Ltd.
No.188 Liduaihua Ave,
Jinxian County
331725 Nanchang, Jiangxi
China

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Sterile Vaginal Dilators for Single Use, Face Masks for Single Use

Notified Body

Date: 2015-08-05

X. Ren

TÜVRheinland LGA Products GmbH Zertifizierungsstelle