TÜVRheinland®

EC Certificate

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

Registration No.: DD 60130835 0001

Report No.: 15096134 007

Manufacturer:
Shaoxing Reborn Medical Devices
Co., Ltd.
1F, Building No.6, Medical
Device Industrial Park
No. 21 Haitian Road, Binhai New Area
Shaoxing
312366 Zhejiang
P.R. China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60117312 0001

Expiry Date: 2022-03-21

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: 2020-09-24

Date: 2020-09-24

Notified Body

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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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60130835 0001
Report No.: 15096134 007

Manufacturer:
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1F, Building No.6, Medical Device Industrial Park
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312366 Zhejiang
P.R. China

Products:

- Disposable Anesthesia Breathing Circuits
- Disposable Breathing Filters
- Catheter Mounts
- Oxygen Masks for Single Use
- Nebulizer Masks for Single Use
- Anesthesia Masks for Single Use
- Closed Suction Catheters for Single Use

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Fuxiu Sheng

Date: 2020-09-24