EC Certificate

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

Registration No.: DD 60133825 0001

Report No.: 15063769 007

Manufacturer:
Ningbo Boya Medical Equipment
Co., Ltd.
10#, No.102, Jingsan Road
Yaobei Industrial Part
315400 YuYao City, Zhejiang Province
China

Digitally signed by Rotari Vladimir
Date: 2022.12.08 07:49:40 MSK
Reason: MoldSign Signature
Location: Moldova

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60089936 0001

Expiry Date: 2023-11-07

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: 2019-01-07

Date: 2019-01-07

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Herbert Zhong

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 60133825 0001
Report No.: 15063769 007

Manufacturer:
Ningbo Boya Medical Equipment Co., Ltd.
10#, No.102, Jingsan Road
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China

Products:

- Breathing System Filters
- Disposable Breathing Circuits
- Heat and Moisture Exchangers
- Disposable Nebulizers
- Anaesthetic Reservoir Bags
- Laryngeal Masks
- Anaesthesia Masks
- PVC Manual Resuscitators

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Herbert Zhong

Date: 2019-01-07