

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Jiangsu Borsun Medical Instrument
Co., Ltd.**
**B007, A District of 5th Floor, B District
of 4th Floor, A District of 4th Floor,
No. 7 Building, No. 1699 Huishan Road,
Huishan Economic Development Zone,
214000 Wuxi Jiangsu
China**

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-12-13
Certificate Registration No.: SX 60144646 0001
An audit was performed. Report No.: 15096024 003
This Certificate is valid until: 2022-03-10

Certification Body



Date 2019-12-13



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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Scope: Products

- Disposable Nebulizers
- Disposable Oxygen Masks
- Disposable Nasal Oxygen Cannulas
- Disposable Connection Tubes
- Disposable Sputum Collectors
- Disposable Sputum Suction Bags
- Disposable Gastrointestinal Tubes
- Urine Drainage Bags
- Infusion Pressure Bags
- Disposable Drainage Bags
- Stool Management Systems
- Negative Pressure Drainage Devices

Certification Body



Date: 2019-12-13



Herbert Zhong