

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

Registration No.: DD 60143297 0001

Report No.: 15096148 006

Manufacturer: Vitalcare (Nanjing) Co., Ltd.
No. 86-8 Shuanggao Road, Gaochun District
Nanjing
211316 Jiangsu
P.R. China

Products: Medical Devices
(see attachment for products included)
Replaces Approval, Registration No.: DD 60120851 0001

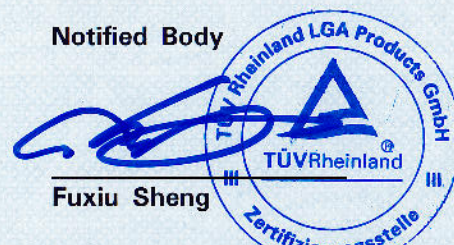
Expiry Date: 2022-06-02

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: 2020-03-19

Date: 2020-03-19

Notified Body



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60143297 0001
Report No.: 15096148 006

Manufacturer: Vitalcare (Nanjing) Co., Ltd.
No. 86-8 Shuanggao Road, Gaochun District
Nanjing
211316 Jiangsu
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Products:

- Sterile Stoma Stoppers
- Disposable Anal Plugs

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile Hydrocolloid Dressings
- Sterile Urine Bags
- Sterile Bile Bags

Aspects of manufacture concerned with conformity of products with the metrological requirements:

- Urine Meter Urine Bags with Measuring Function

Date: 2020-03-19

Notified Body



Fuxiu Sheng

