

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

Registration No.: HD 60149301 0001

Report No.: 17048281 010

Manufacturer: Guangdong Baihe Medical
Technology Co., Ltd.
No.89, Taoyuan East Road
Nanhai, Foshan
528225 Guangdong Province
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60144353 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: 2020-09-16

Date: 2020-09-16

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

Doc. 1/2, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60149301 0001
Report No.: 17048281 010

Manufacturer: Guangdong Baihe Medical
Technology Co., Ltd.
No.89, Taoyuan East Road
Nanhai, Foshan
528225 Guangdong Province
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Products:

- Disposable Suction Catheters
- Disposable Y Introducer Needles
- Disposable Fistula Needles
- Disposable Blood Lines
- Disposable Abdomen Drainage Catheters
- Disposable Endotracheal Tubes
- Disposable Silicone Foley Catheters
- Disposable Nasal Feeding Tubes
- Disposable Drainage Catheters and Accessories
- Disposable Intravenous Cannulas
- Disposable Breathing Circuits
- Disposable Breathing Masks
- Disposable Nasal Oxygen Tubes
- Sterile Scalpels
- Disposable Blood Pressure Transducers & Accessories
- Disposable Haemodialysers
- Disposable Tracheostomy Tubes
- Disposable Guidewires
- Disposable Dilators

Date: 2020-09-16

Notified Body



Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60149301 0001
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Manufacturer: Guangdong Baihe Medical
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- Disposable Injection Site Adapters
- Disposable Stopcocks
- Disposable Infusion Extension Tubes

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Disposable Guidewire Introducer Syringes
- Disposable Sterilizing Brushes
- Disposable Guidewire Advancers

Date: 2020-09-16

Notified Body



Fuxiu Sheng

