

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

**Registration No.:** HD 60144353 0001

**Report No.:** 17048281 009

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

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: HD 60130993 0001

**Expiry Date:** 2024-05-27

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:** 2019-12-02

**Date:** 2019-12-02



**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.:** HD 60144353 0001  
**Report No.:** 17048281 009

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

**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:** 2019-12-02



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
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**Registration No.:** HD 60144353 0001

**Report No.:** 17048281 009

**Manufacturer:** Guangdong Baihe Medical  
Technology Co., Ltd.  
No.89, Taoyuan East Road  
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528225 Guangdong Province  
China

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

- Disposable Guidewire Introducer Syringes
- Disposable Sterilizing Brushes
- Disposable Guidewire Advancers
- Disposable Injection Site Adapters
- Disposable Stopcocks
- Disposable Infusion Extension Tubes

**Date:** 2019-12-02



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Guangdong Baihe Medical  
Technology Co., Ltd.**  
**No.89, Taoyuan East Road  
Nanhai, Foshan  
528225 Guangdong Province  
China**

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

**(see attachment for scope 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: 2018-08-20  
Certificate Registration No.: SX 60130984 0001  
An audit was performed. Report No.: 17048281 005  
This Certificate is valid until: 2021-08-06

Certification Body



Date 2018-08-20



**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**

**Registration No.:** SX 60130984 0001  
**Report No.:** 17048281 005

**Organization:** Guangdong Baihe Medical  
Technology Co., Ltd.  
No.89, Taoyuan East Road  
Nanhai, Foshan  
528225 Guangdong Province  
China

**Scope:** Design and Development, Manufacture and Distribution of  
Disposable Injection Site Adapters, Disposable Stopcocks,  
Disposable Guidewire Introducer Syringes, Disposable  
Infusion Extension Tubes, 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,  
Disposable Sterilizing Brushes, Disposable Guidewire  
Advancers, Sterile Scalpels, Disposable Blood Pressure  
Transducers & Accessories, Disposable Haemodialysers,  
Disposable Tracheostomy Tubes, Disposable Guidewires,  
Disposable Dilators;  
Provision of Ethylene Oxygen Sterilization Service  
in accordance with EN ISO 11135:2014

**Certification Body**



**Date:** 2018-08-20

