

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

**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
P.R. 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: 2020-09-16

Notified Body



Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**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
P.R. China

- 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



EC Certificate



Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2166631-1

Manufacturer: Baihe Medical Technology
(Wuhan) Co.,Ltd.
No.118, Golden Road West
the Ganhe Office
Xiantao City
433000 Hubei
P.R. China

Products: Disposable Blood Lines, Ureteral Stents, Disposable Sterile Stopcock,
Disposable Needle Free Infusion Connectors;
Aspects of manufacture concerned with securing and maintaining sterile
conditions: Antireflux Drainage Bags, Disposable Protective Caps



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.

Report No.: 17063008 009

Effective date: 2021-03-16

Expiry date: 2023-09-12

Issue date: 2021-03-16



Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC DESIGN

Examination Certificate

Certificate No.:
10615-2017-CE-RGC-NA-PS Rev. 1.0

Project No.:
PRJC-127103-2009-PRC-CHN

Valid Until:
27 May 2024

This is to certify that:

Central Venous Catheters

Manufactured by:

Guangdong Baihe Medical Technology Co., Ltd.

No.89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province, P. R. China

Has been assessed with respect to:

**EXAMINATION OF THE DESIGN OF THE PRODUCT AS
DESCRIBED IN ANNEX II SECTION 4 OF COUNCIL
DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 16 December 2019



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html





Management System Certificate

Certificate No.: **241634-2017-AQ-RGC-NA-PS Rev. 1.0** Project No.: **PRJC-24025-2007-MS-C-RGC** Initial Certification Date: **9 August 2004** Valid Until: **26 February 2022**

This is to certify that the management system of:

Guangdong Baihe Medical Technology Co., Ltd.

No.89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province, P.R. China
(Unicode: 91440600721123254C)

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

**Design, Manufacture, Sales and Service of Sterile & Non-sterile Central Venous Catheter Kit, Central Venous Catheter Set, Haemodialysis Catheter Kit, Haemodialysis Catheter Set.
EO Sterilization Services as per ISO 11135-2014.**

Place and Date:
Høvik, 28 February 2019

For:
DNV GL PRESAFE AS



Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info



The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2117242-1

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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918655-100
Effective date: 2021-08-07
Expiry date: 2024-08-06
Issue date: 2021-08-04



Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System
EN ISO 13485:2016

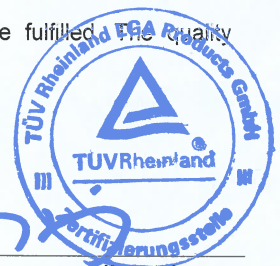
Registration No.: SX 2166631-1

Organization: Baihe Medical Technology
(Wuhan) Co.,Ltd.
No.118, Golden Road West
the Ganhe Office
Xiantao City
433000 Hubei
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable
Blood Lines, Ureteral Stents, Antireflux Drainage Bags, Disposable
Protective Caps, Disposable Sterile Stopcocks, Disposable Needle Free
Infusion Connectors
Provision of Ethylene Oxygen Sterilization Service in accordance with EN
ISO 11135:2014

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918711-100
Effective date: 2021-09-13
Expiry date: 2024-09-12
Issue date: 2021-09-07



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

