

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



TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

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Mail: service@de.tuv.com

Date August 04, 2021

Application for: QMS

Certificate No.: SX 2117242-1

Requirement : EN ISO 13485:2016

Dear Madame or Sir

Enclosed please find the new certificate No. SX 2117242-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Wenxiang Zhang
Certification body



TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

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Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

General Agreement

Company Guangdong Baihe Medical Technology Co., Ltd.
Street No.89, Taoyuan East Road, Nanhai
City Foshan, Guangdong Postcode 528225
Country P.R. China

(hereafter referred to as "Client") and

TÜV Rheinland LGA Products GmbH

(hereafter referred to as "TRLP")

have concluded the following Agreement:

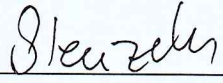
- 1. The Client applies for the right to participate in the TRLP certification system.
- 2. TRLP and the client recognize the

Testing and Certification Regulations of TRLP

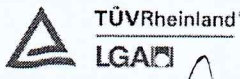

As binding for both parties in all mutual business transactions. This recognition also applies to any future amendments to the above-mentioned document in particular due to new technical developments, changes in legislation, legal situations, court rulings, decisions by competent authorities, accreditation bodies and/ or accreditation requirements as well as market conditions unless the Client terminates this Agreement within one month of receipt of a notification of amendment.
The Client confirms with his signature that he has received the above-mentioned document.

- 3. If the Client concludes a contract with another TÜV Rheinland entity, within the scope of which testing and/or QM system audits and/or certifications, within the meaning of clause 1 of the above-mentioned Testing and Certification Regulations , are to be provided by TRLP, the following order of validity shall apply in this respect in the event of conflicting regulations in terms of content:
a. Testing and Certification Regulations of TRLP
b. General Terms and Conditions of the respective TÜV Rheinland entity
- 4. This Agreement shall be in effect for an initial term ending on December 31st of the current calendar year. It shall be automatically extended by another year unless terminated in writing by one of the parties hereto on or before November 15th of the respective calendar year.
- 5. Should the parties provide the Agreement with an electronic signature; the parties agree that the Agreement shall be signed exclusively electronically in the form of the advanced or qualified signature in accordance with the requirements of the eIDAS Regulation (Regulation (EU) No. 910/2014). In this case, the parties expressly agree to the use of electronic form.
- 6. This Agreement shall be governed exclusively by German substantive law to the exclusion of private international law and the United Nations Convention on Contracts for the International Sale of Goods of 11 April 1980 (UN Sales Convention). Place of jurisdiction for all disputes arising out or in connection with this Agreement shall be Cologne, Germany.

Guangdong , Date 2021-03-30
Place

 Date 15.04.2021
Place


(Legally binding signature)
Appendix: Testing and Certification Regulations of TRLP


Precisely Right.
TÜV Rheinland LGA Products GmbH
Tillystraße 2, D-90431 Nürnberg

(Legally binding signature)