

# 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, Disposable Introducer Sheaths, Disposable Wound Protectors, Disposable Trocars;  
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.

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