

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Bain Medical Equipment  
(Guangzhou) Co., Ltd.  
No. 10, Juncheng Road  
Eastern Area, Economic and  
Technological Development District  
510760 Guangzhou  
P.R. China**

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

**(see attachment for scope and additional site 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: 2020-05-15  
Certificate Registration No.: SX 60148515 0001  
An audit was performed. Report No.: 17038049 017  
This Certificate is valid until: 2023-05-14

Certification Body



Date 2020-05-15



Jing Zhang

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

Doc. 1/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60148515 0001  
**Report No.:** 17038049 017

**Organization:** Bain Medical Equipment  
(Guangzhou) Co., Ltd.  
No. 10, Juncheng Road  
Eastern Area, Economic and  
Technological Development District  
510760 Guangzhou  
P.R. China

**Scope:**

Design and Development, Manufacture and Distribution of  
Disposable A.V. Fistula Needle Sets, Disposable A.V.  
Fistula Needle Sets (Safety Needle series), Disposable  
A.V. Fistula Needle Sets (Dull Needle series with Scab  
remover), Tubing Sets for Hemodialysis, Tubing Sets for  
Blood Purification, Hollow Fiber Dialyzer, Plasmafilters,  
Drain Bags, Disposable Hemodialysis Care Kits,  
Hemodialysis Bicarbonate, Hollow Fiber Membrane,  
Fluid supplementary tubing sets for blood purification;

Provision of Ethylene Oxygen Sterilization Service  
in accordance with EN ISO 11135:2014

**Site included:**

Bain Medical Equipment (Guangzhou) Co., Ltd.  
No.10, Juncheng Road, Eastern Area, Economic and  
Technological Development District, Guangzhou, 510760, China

Design and Development, Manufacture and Distribution of  
Disposable A.V. Fistula Needle Sets, Disposable A.V.

**Certification Body**



**Date: 2020-05-15**



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

Doc. 2/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60148515 0001  
**Report No.:** 17038049 017

**Organization:** Bain Medical Equipment  
(Guangzhou) Co., Ltd.  
No. 10, Juncheng Road  
Eastern Area, Economic and  
Technological Development District  
510760 Guangzhou  
P.R. China

**Scope:**

Fistula Needle Sets (Safety Needle series), Disposable  
A.V. Fistula Needle Sets (Dull Needle series with Scab  
remover), Tubing Sets for Hemodialysis, Tubing Sets for  
Blood Purification, Drain Bags, Disposable Hemodialysis Care  
Kits, Hemodialysis Bicarbonate, Fluid supplementary tubing  
sets for blood purification;  
Design and Development, Distribution of Hollow Fiber  
Dialyzer, Plasmafilters, Hollow Fiber Membrane;

Provision of Ethylene Oxygen Sterilization Service  
in accordance with EN ISO 11135:2014

Site included:  
Bain Medical Equipment (Guangzhou) Co., Ltd.  
No. 10, Banhe Road, Economic and Technological  
Development District, Guangzhou, 510535, China

Manufacture of Hollow Fiber Dialyzer, Plasmafilters,  
Hollow Fiber Membrane

**Certification Body**



**Date:** 2020-05-15

