

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



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

Jing Zhang

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**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

