

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144648 0001

Report No.: 17038049 015

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

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60135861 0001

Expiry Date: 2024-05-14

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: 2020-03-27

Date: 2020-03-27

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

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60144648 0001
Report No.: 17038049 015

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

Products:

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, Disposable Hemodialysis Care Kits,
Plasmafilters, Hemodialysis Bicarbonate, Fluid supplementary
tubing sets for blood purification;

Aspects of manufacture concerned with securing and
maintaining sterile conditions: Drain Bags,
Disposable Hemodialysis Care Kits

Site included:

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

Date: 2020-03-27

Notified Body

Herbert Zhong

