

# EC Certificate



## Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1518511-1

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), 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

Replaces Approval, Registration No.: HD 60144648 0001

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.


Report No.: 10918555-040

Effective date: 2021-05-20

Expiry date: 2024-05-14

Issue date: 2021-05-20



  
Jing Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10, Banhe Road, Economic and Technological Development District, Guangzhou 510535 Guangdong P.R. China	Hollow Fiber Dialyzer, Plasmafilter
/02	Bain Medical Equipment (Guangzhou) Co., Ltd. Floor 1-3 Building A, No. 296, Ruixiang Road, Huangpu District, Guangzhou, 510760 Guangdong P.R. China	Disposable A.V. Fistula Needle Sets, Disposable A.V. Fistula Needle Sets (Safety Needle series), Disposable A.V.Fistula Needle Sets(Dull Needle Series)

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A handwritten signature in blue ink, appearing to read 'Jing Zhang'.

Jing Zhang  
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