

EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.

Doc: BM3-TF-PM-04 (EB) rev.: A.5 24/05/2021



BAIN MEDICAL EQUIPMENT (GUANGZHOU) CO.,LTD

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:

BAIN MEDICAL EQUIPMENT (GUANGZHOU) CO.,LTD

No.10, Juncheng Road, Eastern Area, Economic and Technological Development District, Guangzhou 510760, China.

No.10, Banhe Road, Economic and Technological Development District, Guangzhou 510535, China.

We declare under our sole responsibility that

the medical device: Hollow Fiber Dialyzer

UMDNS Code: 11234 GMDN Code: 47072

Brand Name: DORA

Model codes: B-08PF, B-09PF, B-10PF, B-11PF, B-12PF, B-13PF, B-14PF, B-15PF,B-16PF, B-17PF,B-18PF,B-19PF,B-20PF, B-21PF, B-22PF, B-23PF, B-24PF, B-08HF, B-09HF, B-10HF, B-11HF, B-12HF, B-13HF, B-14HF, B-14H

15HF,B-16HF, B-17HF,B-18HF,B-19HF,B-20HF, B-21HF, B-22HF, B-23HF, B-24HF

of class: Ilb

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: Directive 93/42/EEC Annex II, excluding Section 4

Registration No.: HD1518511-1

Notified Body: TÜV Rheinland LGA Products GmbH

Tillystraße 2 90431 Nürnberg Deutschland CE 0197

Guangzhou, 24/05/2021

MU Fangzhen, Management Representative

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Place, date / Name and function

SECTION CARDINATES (SECTION SECTION SE