Digitally signed by Bolea Petru
Date: 2022.02.17 09:05:24 EET
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Location: Moldova

EC DECLARATION OF CONFORMITY

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

Add.: No.10,Juncheng Road,Eastern Area,GETDD,China.510760 Tel:86-20-82265249 Fax:86-20-32067500 Website:www.bainmedical.com

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

of class: IIb

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
Place, date /

MU Fangzhen, Management Representative
Name and function

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