EC Certificate

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

Registration No.: HD 60138860 0001

Report No.: 17040131 008

Manufacturer:

Jafron Biomedical Co., Ltd.
No. 98, Technology Sixth Road
High-tech Zone
Zhuhai City
519085 Guangdong
China

Products:

- Disposable Hemoperfusion Cartridge
- Disposable Plasma Bilirubin Perfusion Adsorption Column

Replaces Approval, Registration No.: HD 60122976 0001

Expiry Date: 2024-05-27

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: 2019-08-07

Date: 2019-08-07

Notified Body

Fuxiu Sheng

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.

Jafron

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	Jafron Biomedical Co.,Ltd. No.98, Technology Sixth Road, High-tech Zone, Zhuhai City, 519085, Guangdong, China
We declare under our sole responsibility that	
the medical device:	Disposable Hemoperfusion Cartridge model: HA80, HA130, HA180, HA230, HA280, HA330, HA330-Ⅱ, HA380, HA430, HA480 Disposable Plasma Bilirubin Perfusion Adsorption Column model: BS80, BS330, BS380
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.:	**HD 60138860 0001**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**
European Authorized Representative :	**Shanghai International Holding Corp. GmbH (Europe)** **Eiffestrasse 80, 20537 Hamburg, Germany** **Tel: +49-40-2513175**

Zhuhai 2019-08-07
Place, date /

Jianhua Cai Management Representative
Name and function

Jafron Biomedical Co., Ltd.
Add.: No.98, Technology Sixth Road, High-tech Zone, Zhuhai City, 519085, Guangdong, China
Tel: 0086-0756-3619986
www.jafron.com

EC DECLARATION OF CONFORMITY

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

Jafron Biomedical Co., Ltd.
Add.: No.98, Technology Sixth Road, High-tech Zone, Zhuhai City, 519085, Guangdong, China
Tel: 0086-0756-3619986
www.jafron.com