

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

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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.