

**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



**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.