

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60079380 0001

Report No.: 15035757 003

Manufacturer: BioRegen Biomedical (Changzhou)
Co., Ltd.
No.167-5 East East Rd.
213025 Changzhou, Jiangsu
China

Products: Intrauterine Adhesion Barrier Gel

Expiry Date: 2015-10-14

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2012-11-02

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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.