



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 14 11 70340 002

**Manufacturer:** **BioRegen Biomedical (Changzhou) Co., Ltd**  
No. 167-5, East East Road  
213025 Changzhou, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** **Shanghai International Holding Corp. GmbH (Europe)**  
Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):** **Absorbable Adhesion Barrier Gel**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** SH1454101

**Valid from:** 2015-01-20

**Valid until:** 2020-01-19



Hans-Heiner Junker

**Date,** 2015-01-22

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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