

## APPROVAL

EC Directive 93/42/EEC Annex II, Article 3  
Full Quality Assurance System  
Medical Devices

Registration No.: HD 60033210 0001

Report No.: 15035757 001

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

213025 Changzhou, Jiangsu  
China

**Scope:** Design and Development, Manufacture of Nasal/Sinus and  
Otologic Dressing

**Date of Expiry:** 14.10.2015

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Date 15.10.2010



Notified Body

X. Ren

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with.

