

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

**Registration No.:** HD 60041616 0001

**Report No.:** 28411625 001

**Manufacturer:** Vectec S.A.  
Bioparc  
03270 Hauterive  
France

**Scope:** Design/development and manufacturing of disposable  
surgical endoscopic instruments  
  
(see attachments for products included)

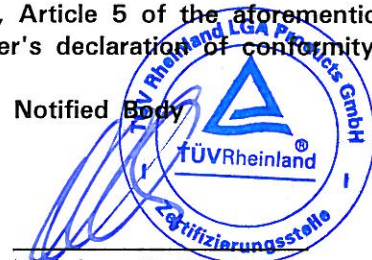
**Date of Expiry:** 18.11.2016

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.

Notified Body

Dipl.-Ing. D. Meier

Date 11.01.2012



**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.



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



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**  
**Registration No.:** HD 60041616 0001  
**Report No.:** 28411625 001

**Manufacturer:** Vectec S.A.  
Bioparc  
03270 Hauterive  
France

**Scope:** Products included:

scissors, forceps, hooks, pneumoperitoneum needles, trocars, retractors for surgical and electrosurgical applications for digestive, gynaecological and urological surgeries.

For following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- oocyte puncture cannula guide
- electrical connection cable

**Date** 11.01.2012

**Certification Body**



**Dipl.-Ing. D. Meier**