



TÜVRheinland®

## APPROVAL

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

Registration No.: HD 60028918 0001

Report No.: 21126049 007

**Manufacturer:** AUROLAB  
No 1, Sivagangai Main road, Veerapanjan  
Madurai 625020  
India

**Scope:** Design/development and manufacture of medical devices  
Products: see attachment  
Replaces approval, registration no.: HD 60021395 0001

**Date of Expiry:** 23.01.2012

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



Date 18.02.2010

Dipl.-Ing. D. Meier

**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. CE

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

**Attachment to**  
**Registration No.:** HD 60028918 0001  
**Report No.:** 21126049 007

**Manufacturer:** AUROLAB  
No 1, Sivagangai Main road, Veerapanjan  
Madurai 625020  
India

**Scope:**

**Products:**

- Implantable PMMA Intraocular Lenses
- Hydrophobic Foldable Intraocular Lenses
- Hydrophilic Foldable Intraocular Lenses and Aspheric Foldable Intraocular Lenses for replacement of the human crystalline lens
- Capsular Tension Rings
- Ophthalmic Solutions
- Ophthalmic Suture Needles
- Micro Surgical Needles
- Ptosis Slings

**Date** 18.02.2010

**Certification Body**

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



TÜVRheinland®

## APPROVAL

EC Directive 93/42/EEC Annex V, Article 3  
Quality Assurance System Production

Registration No.: DD 60028919 0001

Report No.: 21126049 007

**Manufacturer:** AUROLAB  
No 1, Sivagangai Main road, Veerapanjan  
Madurai 625020  
India

**Scope:** Manufacture of Injectors and Cartridges  
for injecting of Foldable Lenses and Ophthalmic  
Surgical Blades

Replaces approval, registration no.: DD 60021398 0001

**Date of Expiry:** 23.01.2012

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body



Date 18.02.2010

Dipl.-Ing. D. Meier

**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).

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