EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60115884 0001

Report No.: 19616252 002

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

Products:
Medical Devices

(see attachment for products included)

Replaces approval, registration no.: HD 60042544 0001

Expiry Date: 2021-12-15

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-12-30

Date: 2016-12-30

Notified Body

X. Ren

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60115884 0001
Report No.: 19616252 002

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

Products:

- PMMA Intraocular Lenses
- Hydrophobic Foldable Intraocular Lenses
- Hydrophilic Foldable Intraocular Lenses
- Hydrophilic Foldable Intraocular Lenses with Injector & Cartridge
- Preloaded Hydrophobic Foldable Intraocular Lenses
- Capsular Tension Rings
- Ophthalmic Solutions
- Non Absorbable Ophthalmic Suture with Needles, Micro Surgical Suture with Needles
- Absorbable Ophthalmic Suture with Needles - Polyglycolic Acid
- Ptosis Slings
- Glaucoma Shunt
- Ophthalmic Surgical Blades

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

X. Ren

Date: 2016-12-30