

EC Certificate

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

Registration No.: HD 2067790-1

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

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.

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Ning N. C. Chang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.