EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60115883 0001

Report No.: 19616252 002

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

Products:
Injectors and Cartridges for injecting of Foldable Lenses

Replaces approval, registration no.: DD 60042543 0001

Expiry Date: 2021-12-15

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III 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.