



**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

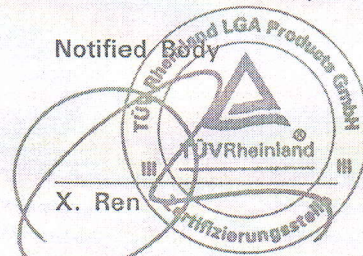
**Products:** Medical Devices  
(see attachment for products included)  
Replaces approval, registration no.: HD 60042544 0001

**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



**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.



*Stef*

TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to  
Certificate

Registration No.: HD 60115884 0001

Report No.: 19616252 002

Manufacturer:

AUROLAB

No 1, Sivagangai Main road, Veerapanjan

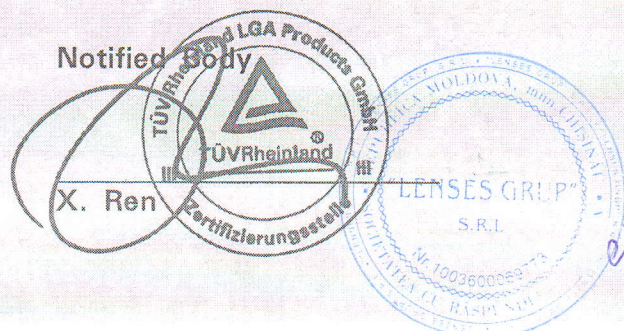
Madurai 625020

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

Date: 2016-12-30





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**Business Stream Products  
Certification Department**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

**AUROLAB**  
No 1, Sivagangai Main road, Veerapa  
MADURAI 625020  
INDIA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date July 20, 2018

**Application for** : QMS Produktion, Anhang V MDD  
**Certificate No.** : DD 60115883 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : Richtlinie 93/42/EWG

Dear Madame or Sir,

The 1st surveillance audit of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above mentioned requirements.

This letter confirms that the above mentioned certificate will remain valid.

Kind regards

Certification body

  
Maciej Sciera

Test sample: no, documentation available

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LGA Products GmbH

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Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

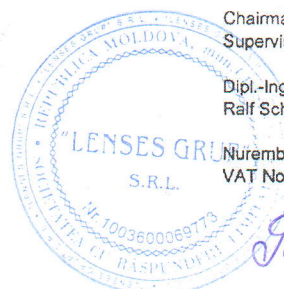
Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nuremberg HRB 26013  
VAT No.: DE 811835490



**Business Stream Products  
Certification Department**

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AUROLAB  
No 1, Sivagangai Main road, Veerapa  
MADURAI 625020  
INDIA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date July 20, 2018

**Application for** : Vollst. QMS, Anhang II MDD  
**Certificate No.** : HD 60115884 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : Richtlinie 93/42/EWG

Dear Madame or Sir,

The 1st surveillance audit of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above mentioned requirements.

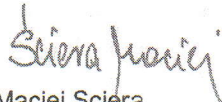
This letter confirms that the above mentioned certificate will remain valid.

Additionally this letter confirms that the new models of Preloaded Hydrophobic Foldable Intraocular Lenses:

- Preloaded Hydrophobic Aspheric Multifocal Foldable IOL, class IIb
  - Preloaded Yellow Hydrophobic Aspheric Foldable IOL, class IIb
- are included in a scope of the certificate.

Kind regards

Certification body

  
Maciej Sciera

Test sample: no, documentation available

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LGA Products GmbH

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Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

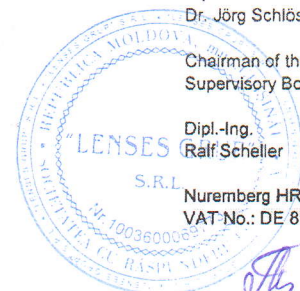
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No 1, Sivagangai Main road, Veerapa  
MADURAI 625020  
INDIA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date July 20, 2018

**Application for** : QMS  
**Certificate No.** : SX 60115885 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : EN ISO 13485:2012  
EN ISO 13485:2012/AC:2012

Dear Madame or Sir,

The 1st surveillance audit of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above mentioned requirements.

This letter confirms that the above mentioned certificate will remain valid.

Kind regards

Certification body

Maciej Sciera

Test sample: no, documentation available

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LGA Products GmbH

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Board of Management

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**Business Stream Products**  
**Certification Department**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

AUROLAB  
No 1, Sivagangai Main road, Veerapa  
MADURAI 625020  
INDIA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date July 20, 2018

**Application for** : QMS Normenkonformität  
**Certificate No.** : SY 60115886 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : EN ISO 9001:2008

Dear Madame or Sir,

The 1st surveillance audit of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above mentioned requirements.

This letter confirms that the above mentioned certificate will remain valid.

Kind regards

Certification body

*Maciej Sciera*

Maciej Sciera

Test sample: no, documentation available

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LGA Products GmbH

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Board of Management

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Chairman of the  
Supervisory Board

Dipl.-Ing.  
Raif Scheller  
Nuremberg HRB 26013  
VAT No.: DE 811835490



# Certificate

Certificate Registration No. : **85 104 001 18076**

Certificate Holder : **Aurolab  
No.1, Sivagangai Main Road,  
Veerapanjan, Madurai - 625020  
India.**

has been assessed and is in  
compliance with the requirements of

**Indian Certification for Medical Devices  
Certification Scheme - ICMED**

**ICMED 13485**

Scope :

**Design and Development, Manufacture and  
Distribution of Medical Devices**

- PMMA Intraocular Lenses
- Hydrophobic Foldable Intraocular Lenses
- Hydrophilic Foldable Intraocular Lenses
- Hydrophilic Foldable Intraocular Lenses with  
Cartridge & Injector
- Preloaded Hydrophobic Foldable Intraocular Lenses
- Capsular Tension Rings
- Keratoprosthesis (KPRO)
- Ophthalmic Solutions



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# Certificate

Certificate Registration No. : **85 104 001 18076**

- Non Absorbable Ophthalmic Suture with Needles
- Micro Surgical Suture with Needles
- Absorbable Ophthalmic Suture with Needles – Polyglycolic Acid
- Ptosis Sling
- Glaucoma Shunt
- Lacrimal intubation set
- Canalicular Stent
- Silicon Sphere
- Iris Retractor
- Ophthalmic Surgical Blades
- Cartridge & Injector

Validity : This certificate is valid from 2018/07/30 until 2021/05/07.



9/03/NABCB/00

Bangalore 2018/07/30

The Certification Body of •  
**TÜV Rheinland (India) Pvt. Ltd.**  
27/B, 2nd Cross Road,  
Electronic City Phase-I,  
Bangalore – 560 100, India.

The validity of this certificate is subject to timely completion of surveillance audits as agreed in the contract.  
The current status of certificate is available on [www.certipedia.com](http://www.certipedia.com)







# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices  
for the following scope:

**Design/development, manufacture and  
distribution of medical devices  
(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012  
EN ISO 13485:2012/AC:2012**

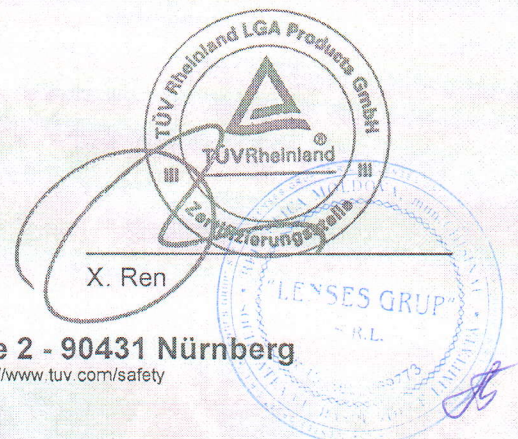
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2016-12-30  
Certificate Registration No.: SX 60115885 0001  
An audit was performed. Report No.: 19616252 002  
This Certificate is valid until: 2019-02-28

Certification Body



Date 2016-12-30



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

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

**Attachment to  
Certificate**

**Registration No.:** SX 60115885 0001  
**Report No.:** 19616252 002

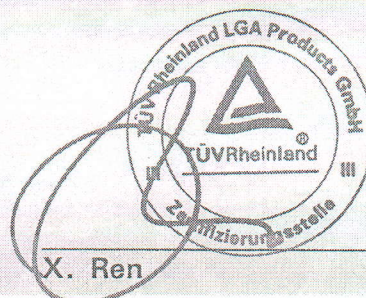
**Organization:** AUROLAB  
No 1, Sivagangai Main road, Veerapanjan  
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India

**Scope:**

**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
- Injector Cartridges and Cartridges for Injecting of Foldable Lenses

**Certification Body**



**Date:** 2016-12-30