

Certificate



Digitally signed by Pereteatco Alina
Date: 2021.10.07 23:07:09 EEST

Certificate Registration No. : **85 102 001 18054**

Audit Report Number : **19616418 002**

Certificate Holder :

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

has been assessed and is in compliance
with the requirements of **ISO 13485:2016**

Scope :

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

- 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,
 - Injectors Cartridges and Cartridges for injecting of Foldable Lenses,
 - Ophthalmic Surgical Instruments
- Design and Development, Manufacture, Distribution,
Installation and Service of Active Ophthalmic Medical
Equipment's such as**
- Green laser Photo Coagulator,
 - Digital Vision Chart,
 - Autorefractor

MS-0035395

Revision: 2020.02.11

www.tuv.com

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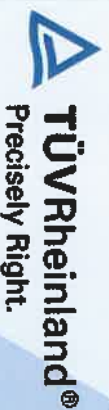
Certificate

Certificate Registration No.: **85 102 001 18054**

Audit Report No.: **19616418 002**

Validity :

This certificate is valid from 2020/03/17 until 2023/02/13



Bangalore
2020/03/17

The Certification Body of
TÜV Rheinland (India) Pvt. Ltd.
27/B, 2nd Cross Road, ~
Electronic City, Phase-1,
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 in www.tuv.com

MS-0035395

Revision: 2020.02.11

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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

Digitally signed by Pereteatco Alma
Date: 2021.10.07 23:07:44 EEST



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.

Report No.: 166450414-50

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25




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.

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

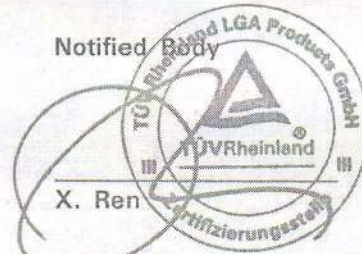
Expiry Date: 2021-12-15

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



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



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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

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

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

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Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
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Dipl.-Ing.
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Nuremberg HRB 26013
VAT No.: DE 811835490





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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

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
Maciej Sciera

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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Board of Management

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Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490





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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

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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Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE-811835490





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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

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

TÜV Rheinland
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Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf 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



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Precisely Right.

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

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

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

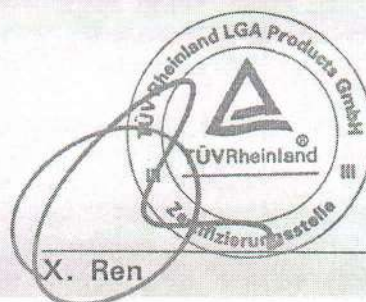
Organization: AUROLAB
No 1, Sivagangai Main road, Veerapanjan
Madurai 625020
India

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

Digitally signed by Pereteatco Alina
Date: 2021.10.08 07:29:03 EEST



nanoCut

ophthalmic surgical blades



Aurolab, with its expertise and experience in ophthalmic consumables, now brings you its range of high end ophthalmic surgical blades — NANOCUT. Nanocut is manufactured from high grade raw material using advanced technology for precise shaping of metal products.

The excellence in manufacturing, displayed in Nanocut, gives surgeons a superior feel while making incisions and entry procedures. It comes with an anti-glare surface that makes it easy to use during surgery. It also has laser depth markings in Clear cornea blades.

Nanocut blades are ETO sterilized and supplied with autoclaveable polycarbonate handles and cradle. Nanocut blades come as a pack of six units.



nanoCut

ophthalmic surgical blades



Stab Knives for initial corneal/ limbal incision

Product Code	Description
S15002	Sideport/ Lancetip/ Stab, 15 degree, straight knife



Slit Knives for phaco incision

K22042	2.2 mm Slit/ Keratome Knife, angled, bi-bevel
K28022	2.8 mm Slit/ Keratome knife, angled, bevel up
K30022	3.0 mm Slit/ Keratome knife, angled, bevel up
K32022	3.2 mm Slit/ Keratome knife, angled, bevel up



Clear Corneal Knives with laser mark showing width/ depth indication marks (1.50 mm, 1.75 mm, 2.00 mm)

K28542	2.85 mm Slit/ Keratome knife, angled, bibevel
K30042	3.00 mm Slit/ Keratome knife, angled, bibevel



Implant Knives for wide/ extend IOL implant

I52022	5.2 mm Blunt tip keratome/ Implant/ Extension knife, angled, bevel up
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Crescent Knives for scleral tunnel incision

C20022	2.0 mm Crescent/ Tunnel incision knife, angled, bevel up
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MVR Knives for micro vitreoretinal surgery

M19002	MVR 19 G knife, straight
M19042	MVR 19 G knife, angled
M20002	MVR 20 G knife, straight
M20042	MVR 20 G knife, angled

Information published in this catalogue is subject to change without notification