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

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

TÜVRheinland®
Precisely Right.

NABCB
QM 010
9/03/NABCB/00

Bangalore
2020/03/17

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 in www.tuv.com

EC Certificate

TÜVRheinland®

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 Alina
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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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.

TÜVRheinland®

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
TÜVRheinland
X. Ren
Zertifizierungsstelle

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

TÜVRheinland®
LGA
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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

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LGA Products GmbH

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90431 Nürnberg

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

TÜVRheinland®
LGA

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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

Sciera Maciej

Maciej Sciera

Test sample: no, documentation available

TÜV Rheinland
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TÜVRheinland®
LGA

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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

TÜV Rheinland
LGA Products GmbH

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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

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
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Web www.tuv.com/safety

Certificate

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

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

has been asssessed 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

"LENSES GRUP" S.R.L.

TÜVRheinland®
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www.tuv.com

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.

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.

9/03/NABCB/00

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

"LENSES GRUP" S.R.L.

TÜVRheinland®
Precisely Right.

www.tuv.com

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2016-12-30

X. Ren

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

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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
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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

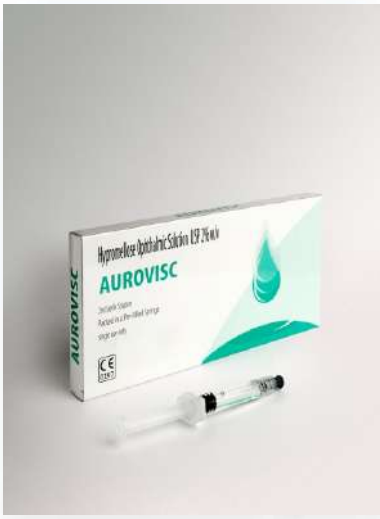
X. Ren

Date: 2016-12-30

AUROVISC

(Hypromellose Ophthalmic Solution 2% w/v)

Premium Quality Viscoelastic Solution



- Consistent physical & chemical properties
- Dual filtration to ensure particle/fiber free solution
- Effective in the protection of corneal endothelium
- Non-antigenic & non-inflammatory

CE
0197

DESCRIPTION

AUROVISC is a viscoelastic solution of high molecular weight, highly purified grade of Hydroxypropyl methylcellulose 2%, clear, isotonic, sterile, non inflammatory and non-pyrogenic in nature. It is used for intraocular injection during anterior segment surgery of the eye.

PROPERTIES

Concentration	: 20 mg/ml (2%)
Molecular Weight	: 86,000 daltons
Viscosity @ 27°C	: 3000 – 4500 cPs
Osmolality	: 250-350 mOsm/kg
pH	: 6.0 – 7.8

CHARACTERISTICS

AUROVISC is a medical device used in the anterior segment surgery of the eye. It has the following unique characteristics:

- It maintains the depth of the anterior chamber of the eye and protects the periocular tissues.
- Outstanding Rheological properties.
- Completely transparent.
- Totally non antigenic.
- Easy to remove from the anterior chamber.
- Does not contain any proteins that are likely to cause any inflammatory reactions and /or foreign body reactions.
- Does not require refrigeration and should not be stored at temperatures above 35°C.
- Does not interfere with the process of Cicatrisation.

INDICATIONS

AUROVISC is indicated as a surgical aid (medical device) in the anterior segment of the eye, including extraction of the lens and insertion of intraocular lenses. It maintains the depth of the anterior chamber during the whole surgical procedure and permits greater operative precision without the risk of damaging the endothelium of the cornea or other intraocular tissues.

PRECAUTIONS

Overfilling the anterior chamber of the eye with AUROVISC may cause increased intraocular pressure, glaucoma or other associated ocular damage. The following precautions are recommended during surgical procedures.

- Do not overfill the eye chamber with Aurovisc.
- AUROVISC should be removed from the anterior chamber at the end of the surgery. Remove as much AUROVISC by irrigation and / or aspiration at the end of the surgery with out jeopardizing the integrity of corneal endothelial cells.
- Carefully monitor intraocular pressure especially during the immediate post operative period. Transient increased IOP may occur following surgery because of pre existing glaucoma or due to surgery itself. If the post operative IOP increases above expected values, treat with appropriate therapy.
- Installation of AUROVISC should be done so as to avoid trapping of air bubbles behind hydroxypropyl methylcellulose solution.
- Avoid reuse of the cannula.
- Although not reported to date, the concurrent presence of medication in the chamber or associated ocular structures may interact with AUROVISC to cause clouding. Physicians should consider this potential if such a phenomenon is observed.

CONTRAINDICATIONS

It is contraindicated in patients with known history of hypersensitivity to its ingredients.

SUPPLY

3 ml, 5 ml vials and 2 ml pre-filled glass syringes.

Information published in this catalogue is subject to change without notification

aurolab

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