

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

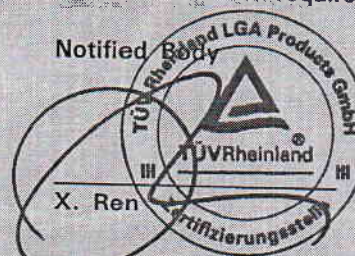
Products: Medical Devices
(see attachment for products included)
Replaces approval, registration no.: HD 60042544 0001

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.

TÜV Rheinland

Doc. 1/1, Rev. 0

LGA Products GmbH

Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60115884 0001

Report No.: 19616252 002

Manufacturer:

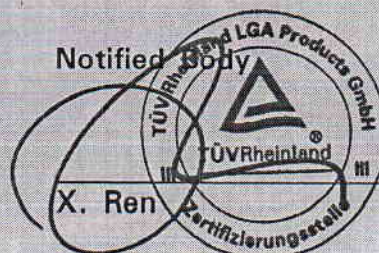
AUROLAB

**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

Date: 2016-12-30



11 January 2017

Dear Sir/ Madam,

This is to conform that the our Client,
"AUROLAB"

No 1 ,Sivagangai Main Road,
Veerapanjan, Madurai- 625020
INDIA

Is covered the following models under directive 93/42/ EEC annex II, Excluding sec 4 . Full quality assurance system certificate Ristration No : **HD 60115884 0001** dated 30th December 2016 and EC Certificate under directive 93/42/ EEC annexV, Production quality assurance certificate Registration No : **DD 60115883 0001** dated 30th December 2016as per our records.

The following models are covered by HD 60115884 0001 dated 30/12/2016

Intraocular lens			
Certificate Name	Product Generic Name	Brand Name	Model Numbers
PMMA Intraocular Lenses	PMMA Intraocular Lens		A5520, A5525, A5528, A5530, A5520R, A5525R, A5527R, A5528R, A5530R, A6028R
			S3525, S3500, S3550, S3600, S3602, S3642, S3652, S3525L, S3500L, S3550L, S3600L, S3602L, S3500R, S3550R, S3600R, S3602R
		Aurolens	SC6530, SM3600, SM3650, SM3600L, SN3600, SN3650, SN3600L, S3602EL, S3550EL, SN3550EL, S3P500, S3P602, S3P550L
			B1602, B3602
		Sightlens	PC 5012, PC 65135, AC 55125, SF6513
		Truedge	S3602SQ, S3600SQ, S3550SQ, S3500SQ, S3550PSQ
	PMMA Square Edge Aspheric Intraocular Lenses	Truedge	S362SQAS
Hydrophilic Foldable Intraocular Lenses	Hydrophilic Foldable Intraocular Lenses	Microfold, Aurofold, Auroflex	FH1575, FH2575, FH3575, FH4575, FH5575, FH6575, FH3600, FH5600, FH5600SQ
	Hydrophilic Foldable		

Hydrophilic Foldable Intraocular Lenses with Injector & Cartridge	Intraocular Lenses with Injector & Cartridge		
		Seeflex	FH6012SQ
		I-Vision	FH 560 I
	Aspheric Foldable Intraocular Lenses	Auroflex EV	FH 5600AS
	Aspheric Foldable Intraocular Lenses with Injector & Cartridge	Seeflex EV	FH6012AS
Hydrophilic Foldable Intraocular Lenses	Toric Foldable Intraocular Lenses	Auroflex Toric	FH 560T 1.5, FH 560T 2.0, FH 560T 2.5, FH 560T 3.0
Hydrophilic Foldable Intraocular Lenses with Injector & Cartridge	Toric Foldable Intraocular Lenses with Injector & Cartridge		
Hydrophobic Foldable Intraocular Lenses	Hydrophobic Foldable Intraocular Lens	Aurovue	HP757SQ, HP7600
		Seevue	HP 60125
	Hydrophobic Aspheric Foldable Intraocular Lens	Aurovue EV	HP7600AS
Preloaded Hydrophobic Foldable Intraocular Lenses	Preloaded Hydrophobic Foldable Intraocular Lens	Aurovue EV Preloaded IOL	HP760AP
		Aurovue EV Toric Preloaded IOL	HP76AT1.5, HP76AT2.0, HP76AT2.5, HP76AT3.0,
Capsular Tension Rings	Capsular Tension Rings	Auroring	CTR10, CTR11, CC10L, CC10R, CC10LR, CC11L, CC11R, CC11LR, CTS, CTRM

Suture Needles			
Certificate Name	Generic Name	Brand Name	Model Numbers
Non absorbable Ophthalmic Suture with Needles	Nylon Sutures with Needles	Aurolon	6401N, 6402N, 6404N, 6491N, 6492N, 6601N, 6602N, 6691N, 6692N, 8401N, 8402N, 8491N, 8492N, 8481N, 8482N, N0204, N6106, N7202
		Seelon	SB-6401N, SB-6402N, SB-6491N, SB-6492N, SB-6601N, SB-6602N, SB-6691N, SB-6692N, SB-8401N, SB-8402N, SB-8491N, SB-8492N, SB-8481N, SB-8482N
Non absorbable Ophthalmic Suture with Needles	Silk Sutures with Needles	Aurosilk	8481S, 8482S, 8481VS, 8482VS, 6482VS, B6105, B6106, B4401, B7102, B7208
		Seesilk	SB-8481S, SB-8482S, SB-8481VS, SB-8482VS, SB-6482VS, SB-B4401, SB-B6105
	Polypropylene Sutures with Needles	Aurolene	6002PP, 60602PP, 6092PP, 60402PP, 60404PP, 60692PP, 60694PP, 8492PP, 8682PP, P9201, P5301, 60992PP, 600922PP, 6992PP, P0204
		Seelene	1025PP, 1030PP
	Polyester Sutures with Needles	Aurobond	E5101, E5102, E4101, E4102, E2202, E2204
Micro Surgical Suture with Needles	Micro Surgical Suture with Needles	Aurolon	N1201, N1233, N1235, N0201, N0204, N0205, N0206, N0207, N0209, N0211, N0212, N0223, N0227, N0229, N0231, N0233, N9203, N9205, N9219, N9220, N9221, N9223, N9225, N9227, N8201, N8202, N8203, N8207, N8209, N8213, N8215, N8229, N2301, N3301, N4401, N5301, N6235, N7201, N7203

Absorbable Ophthalmic Suture with Needles – Polyglycolic Acid	Absorbable Ophthalmic Suture with Needles – Polyglycolic Acid	Polycryl	A6108, A7102, A8104, A9101, A0101, A6303
		Seecryl	A6045, A7030, A8030, A1010
Ptosis Slings	Ptosis Sling	Aurosling	T9052
		See Sling	T6340
Glaucoma Shunt	Glaucoma Shunt	AADI	AADI-350
Pharmaceuticals			
Certificate Name	Generic Name	Brand Name	Model Numbers
Ophthalmic Solutions	Hydroxy Propylmethyl Cellulose 2% w/v	Aurovisc / Seevisc	-----
	Trypan blue 0.06% w/v	Auroblue / Seeblue	
	Perfluoro- n-octane	Aurooctane	
	Silicone oil - 1000cSt (mm2/s)	Aurosil	
	Trypan blue 0.15% w/v	Retiblu / SeeRetblue	
	Silicone oil - 5000cSt (mm2/s)	AurosilPlus	
	Silicone oil - 1500cSt (mm2/s)	Aurosil 1500	
	Brilliant blue G – 0.05% w/v	Ocublu plus/ SeeRetblue plus	
	Sodium hyaluronate 1.4%w/v	Aurogel	
	Sodium hyaluronate 1.6%w/v	Aurogel Plus	

Surgical Blades			
Certificate Name	Generic Name	Brand Name	Model Numbers
Ophthalmic Surgical Blades		Nanocut	Sterile Blades: S15002, C20002, C20022, C20032, K28002, K28022, K28032, K30002, K30022, K30032, K32002, K32022, K32032, K28542, K30042, I52002, I52022, I52032, M19002, M19042, M20002, M20042
			Tip Sterile Blades : S15003, C20003, C20023, C20033, K28003, K28023, K28033, K30003, K30023, K30033, K32003, K32023, K32033, K28543, K30043, I52003, I52023, I52033, M19003, M19043, M20003, M20043
Ophthalmic Surgical Blades	Ophthalmic Surgical Blades	Aurosleek	S10015HC, S13015HC, S16015HC, K22215HC, K22415HC, K28215HC, K28315HC, K28415HC, K30215HC, K30315HC, K32215HC, K32315HC, I52215HC, I52315HC, C25215HC, K28615HC, L15015HC, K275215HC, K275315HC
			S10022HC, S13022HC, S16022HC, S16022HC, C25222HC, K22222HC, K22422HC, K28222HC, K28322HC, K28422HC, K30222HC, K30322HC, K32222HC, K32322HC, I52222HC, I52322HC, I55222HC, I55322HC, C20222HC, L15022HC, S10015HT, S13015HT, S16015HT, K22215HT, K22415HT, K28215HT, K28315HT, K28415HT, K30215HT, K30315HT, K32215HT, K32315HT, I52215HT, I52315HT, C25215HT, K28615HT, L15015HT, K275215HT, K275315HT S10022HT, S13022HT, S16022HT, K22222HT, K22422HT, K28222HT, K28322HT, K28422HT, K30222HT, K30322HT, K32222HT, K32322HT, I52222HT, I52322HT, C25222HT, I55222HT, I55322HT, C20222HT, L15022HT

The following models are covered by DD 60115883 0001 dated 30/12/2016

Generic Name	Generic Name	Brand Name	Model Numbers
Injectors and Cartridges for injecting of Foldable lenses	Injectors and Cartridges	Glide	C100-DI100, C200-DI100, C160-DI100, C300-DI100, C280-DI150, C300-DI150, C290, AC28-DI 100, AC22-DI260Y

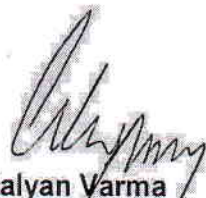
Please contact us if you need any further information or assistance.



Guruprasad HC

Lead Auditor

E-Mail: Guruprasad.hc@ind.tuv.com



G. Kalyan Varma

Vice President, Products

E-Mail: KalyanVa@ind.tuv.com

Head Office:

82/A, West Wing, 3rd Main Road
 Electronics City Phase 1
 Bangalore-560 100, India

Tel. +91 80 6723 3500

+91 80 6723 3610

Fax +91 80 6723 3542

Regional Offices:

Ahmedabad	Mumbai
Chennai	Odisha
Coimbatore	Panchkula
Gurgaon	Pune
Hyderabad	Ranipet
Indore	Tirupur
Jodhpur	Trichy
Kochi	Vadodara
Kolhapur	Visakhapatnam
Kolkata	