bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

USIOL Inc.
also trading as Stephens Instruments
2500 Sandersville Road
Lexington
Kentucky
40511
USA

Holds Certificate Number: **MD 665102**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and distribution of sterile intraocular lenses.
The manufacture and distribution of sterile single use ophthalmic surgical instruments and packs, ophthalmic sutures and ophthalmic solutions.
Design, manufacture and distribution of punctal plugs.

Previous certificate expired on 28/06/2018
Recertification audit ended 11/05/2018

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-05-11
Effective Date: 2018-08-03
Latest Revision Date: 2018-08-03
Expiry Date: 2021-06-18

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Digitally signed by Grabazei Alexandru
Date: 2019.03.28 18:37:18 EET
Reason: MoldSign Signature
Location: Moldova

EC Certification

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding 4 (OBL)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices via an Own Branding arrangement. We certify that the full quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

U.S. IOL INC

2500 Sandersville Road, PO Box 13550, Lexington, KY 40511, USA

Intra Occular Lenses & Sodium Hyaluronate.
As per the Attached Schedule

Certificate Number: 088 G CE
Initial Certification Date: 17 November 2005
Certificate Effective Date: 17 November 2015
Certificate Expiry Date: 16 November 2020

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd

PRODUCT SCHEDULE FOR CERTIFICATE 088 G CE
U.S. IOL INC

OccuLon	Sodium Hyaluronate	1.8%	IIa
OccuLon HV	Sodium Hyaluronate	1.6%	IIa

Mod C Three Piece 850 Series	Length-13.0mm Holes-0 Angle-0 degrees Optic-Equiconvex	IIb
Mod C Single Piece 860 Series	Length-12.5mm Holes-0 Angle-0 degrees Optic-Equiconvex	IIb
Aspheric Single Piece 867 Series	Length-12.5mm Model no.: 865UV, 866UV, 868 UV, 869UV Holes-0 Angle 5 degrees Optic-6mm	IIb
Hydrophobic Single Piece 880 Series	Length-12.5mm Model No.: 880UV Holes-0 Angle-0 degrees Optic-6.0mm	IIb
Mod C Single Piece 860 Series	Length-12.5mm Model No.: 840 UV, 843 UV, 845 UV, 847 UV Holes-0 Angle-0 degrees Optic-Equiconvex	IIb

Initial Certification Date: 17 November 2005
Certificate Effective Date: 17 November 2015

Brian Johnson – Authorized Signatory

EC Certification

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

U.S. IOL INC

2500 Sandersville Road, PO Box 13550, Lexington, KY 40511, USA

Intraocular Lenses
Punctal Plugs

Certificate Number:	**088-02 D CE**
Initial Certification Date:	**13 March 2000**
Certificate Effective Date:	**12 April 2016**
Certificate Expiry Date:	**12 March 2020**

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd

PRODUCT SCHEDULE FOR CERTIFICATE 088-02 D CE
U.S. IOL INC

PMMA	INTRAOCULAR LENSES PRODUCT NUMBER	CLASS
Mod J Single Piece 500 series	Length - 10-17 Holes - 0,1,2,3,4 Angle - 0-10 degrees Optic - Plano, Biconvex, or Step Vault	IIb
L Single Piece 600 series	Length - 12mm Holes - 0 Angle - Step Vault Optic - 5.25mm	IIb
Anterior Chamber 600 Series	Length - 10-17 Holes - 0,1,2,3,4 Angle – 0 - 10 degrees Optic - Plano, Biconvex, or Step Vault	IIb
Mod J Three Piece 100 Series	Length - 10-17 Holes - 0,1,2,3,4 Angle – 0 - 10 degrees Optic - Plano, Biconvex, or Step Vault	IIb
Mod C Three Piece 200 Series	Length - 10-17 Holes - 0,1,2,3,4 Angle – 0 - 10 degrees Optic - Plano, Biconvex, or Step Vault	IIb
Iris Fixated Phakic Lens: 900 Series Lens	Length – 10.30 Holes – 4 Single Piece Angle: Step Vault Optic: Miniscus	IIb
Acrylic Lens Single Piece 860UV Series Also labeled as **860 UV, 862 UV, 863 UV, 864 UV, 867-UV, 868-UV**	Length – 12.5mm Holes - 0 Angle – 0 degrees Optic – Biconvex	IIb

Initial Certification Date: 22 July 1997
Certificate Effective Date: 12 April 2016

Brian Johnson – Authorized Signatory

MATAC Certification Services Limited
Davy Avenue, Knowlhill, Milton Keynes MK5 8NL, UK
Telephone +44 (0)1908 857 750, Fax +44 (0)1908 857 751, www.matac-acs.com, Email: acs@intertek.com
Registered No. 829615 Registered Office

PRODUCT SCHEDULE FOR CERTIFICATE 088-02 D CE
U.S. IOL INC

Hydrophillic Lens Single Piece
867Series Length – 12.5mm — IIb
Model No.867-UV, 871UV, 872UV, 873UV
Holes - 0
Angle – 5 degrees
Optic – Biconvex

Hydrophillic Lens Single Piece
868Series Length – 12.5mm — IIb
Model No.831UV, 832UV, 833UV, 868-UV
Holes - 0
Angle – 5 degrees
Optic – Biconvex

Mod C Single Piece 600 series — IIb
Length - 10-17
Holes - 0,1,2,3,4
Angle – 0 - 10 degrees
Optic - Plano, Biconvex, or Step Vault

Lacrivera VeraPlug: — IIb
VSP-1002 VERAPLUG, Silicone Punctum Plug, 1.65mm
VSP-1003 VERAPLUG, Silicone Punctum Plug, 1.83mm
VSP-1004 VERAPLUG, Silicone Punctum Plug, 2.00mm

BNS-1002 VERAPLUG,Silicone Punctum Plug 1.65mm — IIb
BNS-1003 VERAPLUG,Silicone Punctum Plug 1.83mm
BNS-1004 VERAPLUG,Silicone Punctum Plug 2.00mm

Initial Certification Date: 22 July 1997
Certificate Effective Date: 12 April 2016

Brian Johnson ~ Authorized Signatory

ASTAC Certification Services Limited
Davy Avenue, Knowlhill, Milton Keynes MK5 8NL, UK
Telephone +44 (0)1908 857 750, Fax +44 (0)1908 857 751, www.intertek-astac.com Email: astac@intertek.com
Registered No. 829615 Registered Office

EC Certification

PRODUCTION QUALITY ASSURANCE
Directive 93/42/EEC for Medical Devices, Annex V (OBL)

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices via an Own Branding arrangement. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

U.S. IOL INC

2500 Sandersville Road, PO Box 13550, Lexington, KY 40511, USA

Sutures, Sterile Single Use Lens Injector and Cartridge, US Gel.
As per the Attached Schedule

Certificate Number:	**088 E CE**
Initial Certification Date:	**17 November 2005**
Certificate Effective Date:	**17 November 2015**
Certificate Expiry Date:	**16 November 2020**

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd

PRODUCT SCHEDULE FOR CERTIFICATE 088 E CE
U.S. IOL INC

US Gel	HPMC	1.800%	IIa
Sutures			
US-1001LZS	Silk, multifi		IIa
US-9001LZS	Silk, multifil		IIa
US-8001LZS	Silk, multifil		IIa
US-7001LZS	Silk, multifil		IIa
US-6001LZS	Silk, multifil		IIa
US-5001LZS	Silk, multifil		IIa
US-1002LZS	Silk, multifil		IIa
US-9002LZS	Silk, multifil		IIa
US-8002LZS	Silk, multifil		IIa
US-7002LZS	Silk, multifil		IIa
US-6002LZS	Silk, multifil		IIa
US-5002LZS	Silk, multifil		IIa
US-1001LZN	Nylon (Polyamide), monofili		IIa
US-9001LZN	Nylon (Polyamide), monofili		IIa
US-8001LZN	Nylon (Polyamide), monofili		IIa
US-7001LZN	Nylon (Polyamide), monofili		IIa
US-6001LZN	Nylon (Polyamide), monofili		IIa
US-5001LZN	Nylon (Polyamide), monofili		IIa
US-1002LZN	Nylon (Polyamide), monofili		IIa
US-9002LZN	Nylon (Polyamide), monofili		IIa
US-8002LZN	Nylon (Polyamide), monofili		IIa
US-7002LZN	Nylon (Polyamide), monofili		IIa
US-6002LZN	Nylon (Polyamide), monofili		IIa
US-5002LZN	Nylon (Polyamide), monofili		IIa
US-2001RCN	2/0 Suture, Non absorbable, Synthetic Polyamide, Single Armed		IIa
US-2002LZN	2/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-3001RCN	3/0 Suture, Non absorbable, Synthetic Polyamide, Single Armed		IIa
US-3002LZN	3/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-4001LZN	4/0 Suture, Non absorbable, Synthetic Polyamide, Single Armed		IIa
US-4002LZN	4/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-5001RCN	5/0 Suture, Non absorbable, Synthetic Polyamide, Single Armed		IIa
US-5002LZN	5/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-6001LZN	6/0 Suture, Non absorbable, Synthetic Polyamide, Single Armed		IIa
US-6002LZN	6/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-7001LZN	7/0 Suture, Non absorbable, Synthetic Polyamide, Single Armed		IIa
US-7002LZN	7/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-8002LZN	8/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-9002LZN	9/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-1002LZN	10/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-1101LZN	11/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa
US-1102LZN	11/0 Suture, Non absorbable, Synthetic Polyamide, Double Armed		IIa

Initial Certification Date: 17 November 2005
Certificate Effective Date: 17 November 2015

Brian Johnson – Authorized Signatory

AMTAC Certification Services Limited
Davy Avenue, Knowlhill, Milton Keynes MK5 8NL, UK
Telephone +44 (0)1908 [illegible] Fax +44 (0)1908 [illegible] Email [illegible]
Registered No. [illegible] Registered Office

PRODUCT SCHEDULE FOR CERTIFICATE 088 E CE
U.S. IOL INC

US-8002LZS 11/0 Suture, Non absorbable, Silk, Double Armed	IIa
US-6002LZV 6/0 suture, vicryl, double armed	IIa
US-8002LZV 8/0 suture, vicryl, double armed	IIa
US-9001LZV 9/0 suture, vicryl, double armed	IIa
Sterile Single Use Lens Injector and Cartridge US-2000 Series	IIa

Initial Certification Date: 17 November 2005
Certificate Effective Date: 17 November 2015

Brian Johnson – Authorized Signatory

ANTAC Certification Services Limited
Davy Avenue, Knowlhill, Milton Keynes MK5 8NL, UK
Telephone +44 (0) 1908 857 750, Fax +44 (0) 1908 857 751, www.intertek-antac.com Email: acs@intertek.com
Registered No. 829815 Registered Office

Declaration of Conformity

MANUFACTURER:

USIOL, INC.
2500 SANDERSVILLE ROAD
LEXINGTON, KY 40511
UNITED STATES

EUROPEAN REPRESENTATIVE:

EC REP

EMERGO GROUP
PRINSESSEGRACHT 20
2514 AP THE HAGUE
THE NETHERLANDS

MEDICAL DEVICE:

INTRAOCULAR LENSES
PUNCTAL PLUGS

CLASSIFICATION - ANNEX IX:

CLASS IIB

CONFORMITY ASSESSMENT ROUTE:

ANNEX II

WE, STEPHENS INSTRUMENTS, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION IN TO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42 EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES - AS AMENDED BY DIRECTIVE 2007/47/EC ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: SEE TECHNICAL FILE FOR LIST OF STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY:

INTERTEK
DAVY AVENUE, KNOWLHILL
MILTON KEYNES, BUCKS, MK5 8NL
UNITED KINGDOM

IDENTIFICATION NUMBER:

CE 0473

(CE) CERTIFICATE(S):

088G CE

START OF CE MARKING:

22 July 1997

PLACE OF DECLARATION

USIOL, INC.
2500 SANDERSVILLE ROAD
LEXINGTON, KY 40511
UNITED STATES

ARCHNA JOHNSON
VICE PRESIDENT

DATE: 24 AUGUST 2017