

Intertek

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

Intertek

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

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

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

Intertek

Hydrophilic Lens Single Piece

867Series Length - 12.5mm
Model No.867-UV, 871UV, 872UV, 873UV
Holes - 0
Angle - 5 degrees
Optic - Biconvex

IIb

Hydrophilic Lens Single Piece

868Series Length - 12.5mm
Model No.831UV, 832UV, 833UV, 868-UV
Holes - 0
Angle - 5 degrees
Optic - Biconvex

IIb

Mod C Single Piece 600 series

Length - 10-17
Holes - 0,1,2,3,4
Angle - 0 - 10 degrees
Optic - Plano, Biconvex, or Step Vault

IIb

Lacrivera VeraPlug:

VSP-1002 VERAPLUG, Silicone Punctum Plug, 1.65mm
VSP-1003 VERAPLUG, Silicone Punctum Plug, 1.83mm
VSP-1004 VERAPLUG, Silicone Punctum Plug, 2.00mm

IIb

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

IIb

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Brian Johnson ~ Authorized Signatory

EC Certification

Intertek

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



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.
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PRODUCT SCHEDULE FOR CERTIFICATE 088 E CE

U.S. IOL INC

Intertek

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

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

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US-8002LZS 11/0 Suture, Non absorbable, Silk, Double Armed
US-6002LZV 6/0 suture, vicryl, double armed
US-8002LZV 8/0 suture, vicryl, double armed
US-9001LZV 9/0 suture, vicryl, double armed

Ila
Ila
Ila
Ila

Sterile Single Use Lens Injector and Cartridge
US-2000 Series

Ila

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