

REVISION HISTORY		
REV	ECN	DATE
A	20050962	8/5/05
B	20060455	4/11/06
C	20060606	5/17/06
D	20100428	3/18/10
E	20101461	9/1/10

DECLARATION OF CONFORMITY
for the
Medical Device Directive 93/42/EEC

FOR

OPHTHALAS 532 EYELITE LASER SYSTEM

By:	Date:	 IRVINE, CALIFORNIA
R. Elgas	7-14-05	
Checked:	Date:	
Juli Brush	7/22/05	
Approved:	Date:	
R. Elgas	7/22/05	

Title:	Drawing Number:	Revision:
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DECLARATION OF CONFORMITY

for the

Medical Device Directive 93/42/EEC

Annex II ☐

Annex III / V ☐
Annex VII / V ☐

Annex VII ☒

Article 12 ☐
Article 12 / Annex V ☐

Date of Issuance: August 31, 2010

Supersedes Declaration Dated: March 18, 2010

Manufacturer: Alcon Laboratories Inc., 6201 South Freeway, Fort Worth, Texas 76134-2099, U.S.A.

Authorized European

Union Representative: Alcon Laboratories (U.K) Ltd., Boundary Way, Hemel Hempstead, Hertfordshire, HP2 7 UD, United Kingdom

Product: See the attached list for the Catalog Number, MDD Class, and Item Description.

EC Certificate Category: Surgical Devices and Electrosurgical Products for use in Ophthalmologic Procedures (Cataract, Vitreoretinal, Laser, and Imaging)

Technical File Title: Ophthalas 532 EyeLite System

This declaration is applicable to all products listed and manufactured after the date of issuance of this declaration of conformity.

We hereby declare under our sole responsibility that the listed device(s) and quality system conform to:

MDD 93/42/EEC:1993 *as amended*

Annex II Certificate: (Applicable only if declaration is under Annex II): TUV SUD Product Service, Ridlerstr. 65, D-80339 Muenchen, Germany

Standards Applied: Refer to Technical File Index section 2.
ISO 13485:2003

☒ Article 12 [Check for systems (e.g. Kits) / Procedure Pack(s)]:
We have verified the (a) mutual compatibility of the devices in accordance with the manufacturer(s) instructions and carried out our operations in accordance with these instructions. We have (b) packaged the product and supplied relevant information to users incorporating relevant instructions from the manufacturer(s). (c) The whole activity is subject to appropriate methods of internal control or inspection. (d) If the device(s) is sterilized, it was processed in accordance with Annex V of the MDD and the manufacturer(s) instructions.

Signed:



Signed:



Dan Modi
ITC R&D Quality System Management Representative
Alcon Laboratories, Inc.
6201 South Freeway, Fort Worth, TX 76134-2009,
U.S.A.

Denis Faunce
Site-Wide Quality System Management Representative
Alcon Laboratories, Inc.
6201 South Freeway, Fort Worth, TX 76134-2009, U.S.A.

Title:

DOC, EYELITE LASER ARTICLE 12

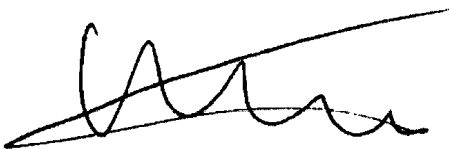

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Signed: 	Signed: 
Bruno Dacquay Surgical Instrumentation, R&D - Medical Specialty Director Alcon Laboratories, Inc. 6201 South Freeway, Fort Worth, TX 76134-2009, U.S.A.	Martin Kaufman ITC Regulatory Affairs Alcon Laboratories, Inc. 6201 South Freeway, Fort Worth, TX 76134-2009, U.S.A.

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**Attachment to the
DECLARATION OF CONFORMITY
for the Medical Device Directive 93/42/EEC
FOR
OPHTHALAS 532 EYELITE LASER SYSTEM**

Item #	Catalog Number	MDD Class	GMDN Code	Item Description
1	8065740982	I	SBV	Slit Lamp, CSO SL1000
2	8065-0050-01	I	SBV	Slit Lamp, Haag-Streit 900 BM

SBV = To be supplied by manufacturer.

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