

REVISION HISTORY		
REV	ECN	DATE
P1	NOT REL	3/28/08
A	20080966	3/28/08
B	20080985	3/31/08

EC DECLARATION OF CONFORMITY
FOR
NGL – NEXT GENERATION LASER

By: Bryan Somen

Date: 3/28/08

Checked: Paul Pynckel

Date: 3/28/08

Approved: Chris Horvath

Date: 3/28/08

Alcon[®]

IRVINE, CALIFORNIA

Title:

DOC, NEXT GEN LASER

Drawing Number:

931-4120-001

Revision:

B

Sheet 1 of 3

EC DECLARATION OF CONFORMITY

Annex II ☒

Annex III / V ☐

Annex VII / V ☐

Annex VII ☐

Article 12 ☐

Article 12 / Annex V
☐

Date: March 31, 2008

Supersedes Declaration dated: March 28, 2008

Manufacturer: Alcon Laboratories Inc., 6201 South Freeway, Fort Worth, Texas 76134, USA.

Authorized European Representative: Alcon Laboratories (U.K) Ltd. Boundary Way, Hemel Hempstead, Hertfordshire, HP2 7UD, U.K.

Product: See attached list for Catalog Number and starting revision.

Technical File Title: NGL – Next Generation Laser

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) under quality systems at Alcon, 15800 Alton Parkway, Irvine, CA 92618, USA conform(s) to:

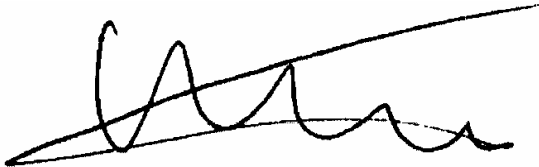
MDD 93/42/EEC:1993 (*amended by directives 98/79/EC, 2000/70/EC, 2001/104/EC, 2003/12/EC and 2003/32/EC*)

Notified Body: TUV SUD Product Service, Ridlerstr, 65, D-80339 Muenchen, Germany.

Standards Applied: Refer to Technical File Index section 2.

- ☐ 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:



Bruno Dacquay
R&D Quality System Management Representative
Alcon Research Ltd.
Irvine, CA 92618, U.S.A

Signed:



Denis Faunce
Facility's Site Wide Quality System
Management Representative
Alcon Research Ltd.
Irvine, CA 92618, U.S.A

Title:

DOC, NEXT GEN LASER

Drawing Number:

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B

Sheet 2 of 3

**ATTACHMENT TO
EC DECLARATION OF CONFORMITY
For
NGL – NEXT GENERATION LASER SYSTEM**

[illegible]

Title: <div style="text-align: center;">DOC, NEXT GEN LASER</div>	Drawing Number: <div style="text-align: center;">931-4120-001</div>	Revision: <div style="text-align: center;">B</div>
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