

REVISION HISTORY		
REV	ECN	DATE
D	20100276	2/24/10
E	20100947	6/17/10
F	20102120	12/10/10
G	CN014548ECN	2/23/11
H	CN015512ECN	3/10/11

DECLARATION OF CONFORMITY
for the
Medical Device Directive 93/42/EEC
FOR
CONSTELLATION® VISION SYSTEM

By:
John Underwood

Date:
8-30-08

Checked:
Paul Pynckel

Date:
8/30/08

Approved:
Roger Thomas

Date:
8/30/08

Alcon®
IRVINE, CALIFORNIA

Title:

DOC, MDD CONSTELLATION

Drawing Number:

931-2350-002

Revision:

H

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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: March 10, 2011

Supersedes Declaration Dated: February 22, 2011

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: CONSTELLATION® VISION 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:



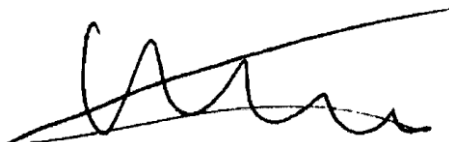
Signed:




Dan Modi
SIR&D Quality System Management Representative
Alcon Laboratories, Inc.
6201 South Freeway, Fort Worth, TX 76134-2099, U.S.A.

Linda Howe Garriz
Site-Wide Quality System Management Representative
Alcon Laboratories, Inc.
6201 South Freeway, Fort Worth, TX 76134-2099, U.S.A.

Signed:



Signed:



Bruno Dacquay
Surgical Instrumentation R&D Head
Alcon Laboratories, Inc.
6201 South Freeway, Fort Worth, TX 76134-2099, U.S.A.

Martin Kaufman
ITC Regulatory Affairs
Alcon Laboratories, Inc.
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**Attachment to the
DECLARATION OF CONFORMITY
for the Medical Device Directive 93/42/EEC
FOR
Constellation[®] Vision System**

Item #	Catalog Number	MDD Class	GMDN Code	Item Description
1	8065751145	IIb	45073	Constellation [®] Vision System with PurePoint [®] Laser
2	8065751147	IIb	45073	Constellation [®] Vision System without Laser
3	8065751150	IIb	45073	Constellation [®] Table Top
4	8065751450	IIb	N/A*	Constellation [®] Embedded Laser
5	8065751451	IIb	N/A*	Constellation [®] Base
6	8065751452	IIb	N/A*	Constellation [®] Aux Illuminator
7	8065751539	IIb	N/A*	Constellation [®] Tray Arm Assy
8	8065751540	IIb	N/A*	Constellation [®] Ballast
9	8065751541	IIb	N/A*	Constellation [®] Support Column
10	8065751548	IIb	45073	Constellation [®] XT
11	8065751549	IIb	45073	Constellation [®] LT
12	8065751550	IIb	45073	Constellation [®] LXT
13	8065751551	IIb	45073	Constellation [®] LX
14	8065751552	IIb	45073	Constellation [®] B
15	8065751553	IIb	45073	Constellation [®] X
16	8065751554	IIb	45073	Constellation [®] L
17	8065751558	IIb	45073	Constellation [®] T
18	8065751536	IIb	45073	Constellation [®] Table Top China
19	8065751598	IIb	45073	Constellation [®] XT China
20	8065751601	IIb	45073	Constellation [®] LXT China
21	8065751597	IIb	45073	Constellation [®] B China
22	8065751594	IIb	45073	Constellation [®] L China
23	8065751559	IIb	N/A*	Constellation [®] Tray Arm Kit
24	8065750968	IIb	36362	Constellation [®] Remote Control
25	8065750977	IIb	36336	Constellation [®] Footswitch
26	8065751694	IIb	N/A*	Constellation [®] Pneumatic Pressure Hose
27	8065751817	IIb	45073	Constellation [®] Table Top Japan
28	8065752041	IIb	45073	Constellation [®] XT Japan
29	8065752042	IIb	45073	Constellation [®] LT Japan
30	8065752043	IIb	45073	Constellation [®] LXT Japan
31	8065752044	IIb	45073	Constellation [®] T Japan

*The indicated catalog numbers are accessories/modules integrated into the Constellation[®] Vision System.

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