

REVISION HISTORY		
REV	ECN	DATE
C	20100222	2/12/10
D	20110035	1/11/11
E	20110085	1/20/11
F	CN014408ECN	6/7/11
G	CN020638ECN	8/15/11

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

By:

Eric Lee

Date:

8/25/08

Checked:

Tiffany Sutliff

Date:

8/27/08

Approved:

Eric Lee

Date:

8/28/08

Alcon®
IRVINE, CALIFORNIA

Title:

DOC,MDD,CONSTELLATION CONS

Drawing Number:

931-2380-001

Revision:

G

Sheet 1 of 8

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

Annex II <input checked="" type="checkbox"/>	Annex III / V <input type="checkbox"/> Annex VII / V <input type="checkbox"/>	Annex VII <input type="checkbox"/>	Article 12 <input type="checkbox"/> Article 12 / Annex V <input type="checkbox"/>
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Date of Issuance: August 15, 2011

Supersedes Declaration Dated: June 2, 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® Consumables

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

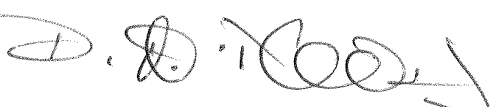
We hereby declare under our sole responsibility that the listed device(s) and quality system conform to:


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

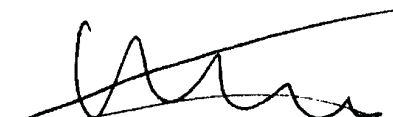
☐ **Article 12 [Check for systems (e.g. Kits) / Procedure Pack(s)]:**
We have verified the (a) mutual compatibility of the devices in accordance with the manufacturer(s) instructions and carried out our operations in accordance with these instructions. We have (b) packaged the product and supplied relevant 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.

Dick Wells
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.
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Martin Kaufman
ITC Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway, Fort Worth, TX 76134-2099, U.S.A.

Title: <div style="text-align: center; font-weight: bold; font-size: 1.2em;">DOC,MDD,CONSTELLATION CONS</div>	Drawing Number: <div style="text-align: center; font-weight: bold;">931-2380-001</div>	Revision: <div style="text-align: center; font-weight: bold;">G</div>
Sheet 2 of 8		

**Attachment to the
DECLARATION OF CONFORMITY
for the Medical Device Directive 93/42/EEC
FOR
Constellation® Consumables**

Item #	Catalog Number	MDD Class	GMDN Code	Item Description
Constellation® Vitrectomy Paks				
1.	8065751514	Ilb	45150	CONSTELLATION VIT BASIC PAK
2.	8065752034	Ilb	45150	CONSTELLATION VIT BASIC PAK, Japan
3.	8065751063	Ilb	45150	20GA TOTALPLUS® Vit Pak- 5000CPM
4.	8065751057	Ilb	45150	20GA TOTALPLUS® Vit Pak- 5000CPM Wide
5.	8065751059	Ilb	45150	20GA TOTALPLUS® Vit Pak- 2500CPM
6.	8065751061	Ilb	45150	20GA TOTALPLUS® Vit Pak- 2500CPM Wide
7.	8065752024	Ilb	45150	20GA TOTALPLUS® Vit Pak 5000CPM J
8.	8065751058	Ilb	45150	23GA TOTALPLUS® Vit Pak- 5000CPM
9.	8065751157	Ilb	45150	23GA TOTALPLUS® Vit Pak- 5000CPM Wide
10.	8065751062	Ilb	45150	23GA TOTALPLUS® Vit Pak- 2500CPM
11.	8065751453	Ilb	45150	23GA TOTALPLUS® Vit Pak- 2500CPM Wide
12.	8065751613	Ilb	45150	23GA TOTALPLUS® Vit Pak 7500CPM Valve
13.	8065751614	Ilb	45150	23GA TOTALPLUS® Vit Pak 7500CPM Valve Wide
14.	8065751900	Ilb	45150	23GA TOTALPLUS® Vit Pak- 5000CPM Valved
15.	8065751901	Ilb	45150	23GA TOTALPLUS® Vit Pak- 5000CPM Wide Valved
16.	8065752026	Ilb	45150	23GA TOTALPLUS® Vit Pak- 5000CPM J
17.	8065752030	Ilb	45150	23GA TOTALPLUS® Vit Pak- 7500CPM Valved J
18.	8065752035	Ilb	45150	23GA TOTALPLUS® Vit Pak- 5000CPM Valved J
19.	8065751060	Ilb	45150	25GA TOTALPLUS® Vit Pak- 5000CPM
20.	8065751156	Ilb	45150	25GA TOTALPLUS® Vit Pak- 5000CPM Wide
21.	8065751056	Ilb	45150	25GA TOTALPLUS® Vit Pak- 2500CPM
22.	8065751454	Ilb	45150	25GA TOTALPLUS® Vit Pak- 2500CPM Wide
23.	8065751462	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 5000CPM
24.	8065751463	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 5000CPM Wide
25.	8065751464	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 2500CPM
26.	8065751465	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 2500CPM Wide
27.	8065751617	Ilb	45150	25+™ TOTALPLUS® 7500CPM Valve
28.	8065751618	Ilb	45150	25+™ TOTALPLUS® 7500CPM Valve Wide
29.	8065751902	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 5000CPM Valved
30.	8065751903	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 5000CPM Wide Valved
31.	8065752028	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 5000CPM J
32.	8065752032	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 7500CPM Valved J
33.	8065752037	Ilb	45150	25+™ TOTALPLUS® Vit Pak- 5000CPM Valved J

Title: DOC,MDD,CONSTELLATION CONS	Drawing Number: 931-2380-001	Revision: G
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**Attachment to the
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FOR
Constellation® Consumables**

Item #	Catalog Number	MDD Class	GMDN Code	Item Description
Constellation® Phaco Paks				
34.	8065751155	Ila	45150	0.9 mm Tipless Phaco Pak
35.	8065751158	Ila	45150	1.1 mm Tipless Phaco Pak
Constellation® Combined Procedure Paks				
36.	8065751070	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM/1.1mm
37.	8065751064	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM WD/ 1.1mm
38.	8065751079	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM/0.9mm
39.	8065751076	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM WD/ 0.9mm
40.	8065751066	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 2500CPM/1.1mm
41.	8065751067	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 2500CPM WD/1.1mm
42.	8065751078	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 2500CPM/0.9mm
43.	8065751074	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 2500CPM WD/ 0.9mm
44.	8065751080	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM
45.	8065751085	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM Wide
46.	8065752009	Ilb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM J
47.	8065751065	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM/1.1mm
48.	8065751160	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM WD/ 1.1mm
49.	8065751077	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM/0.9mm
50.	8065751154	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM WD/ 0.9mm
51.	8065751069	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 2500CPM/1.1mm
52.	8065751455	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 2500CPM WD/ 1.1mm
53.	8065751075	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 2500CPM/0.9mm
54.	8065751457	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 2500CPM WD/ 0.9mm
55.	8065751083	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM
56.	8065751678	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM Wide
57.	8065751765	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 7500CPM Valve/0.9mm
58.	8065751766	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 7500CPM Valve Wide/0.9mm
59.	8065751908	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM Valved/0.9mm
60.	8065751909	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM Wide Valved/0.9mm
61.	8065752011	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM J
62.	8065752012	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 7500CPM Valved/0.9mm J
63.	8065752020	Ilb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM Valved/0.9mm J
64.	8065751071	Ilb	45150	25GA TOTALPLUS® Comb Proc Pak 5000CPM/1.1mm
65.	8065751161	Ilb	45150	25GA TOTALPLUS® Comb Proc Pak 5000CPM WD/ 1.1mm

Title: DOC,MDD,CONSTELLATION CONS	Drawing Number: 931-2380-001	Revision: G
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Constellation® Consumables**

Item #	Catalog Number	MDD Class	GMDN Code	Item Description
66.	8065751072	IIb	45150	25GA TOTALPLUS® Comb Proc Pak 5000CPM/0.9mm
67.	8065751159	IIb	45150	25GA TOTALPLUS® Comb Proc Pak 5000CPM WD/ 0.9mm
68.	8065751068	IIb	45150	25GA TOTALPLUS® Comb Proc Pak 2500CPM/1.1mm
69.	8065751456	IIb	45150	25GA TOTALPLUS® Comb Proc Pak 2500CPM WD/ 1.1mm
70.	8065751073	IIb	45150	25GA TOTALPLUS® Comb Proc Pak 2500CPM/0.9mm
71.	8065751458	IIb	45150	25GA TOTALPLUS® Comb Proc Pak 2500CPM WD/ 0.9mm
72.	8065751466	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM /1.1mm
73.	8065751467	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM WD/ 1.1mm
74.	8065751468	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM /0.9mm
75.	8065751469	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM WD/0.9 mm
76.	8065751470	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 2500CPM /1.1mm
77.	8065751471	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 2500CPM WD/1.1mm
78.	8065751472	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 2500CPM /0.9mm
79.	8065751473	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 2500CPM WD/0.9 mm
80.	8065751687	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM
81.	8065751688	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM Wide
82.	8065751767	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 7500CPM Valve/0.9mm
83.	8065751768	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 7500CPM Valve Wide/0.9mm
84.	8065751910	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM Valved/0.9mm
85.	8065751911	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM Wide Valved/0.9mm
86.	8065752015	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 7500CPM Valved/0.9mm J
87.	8065752017	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM J
88.	8065752022	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM Valved/0.9mm J
89.	8065751070/ FE Lot # P1083558H	IIb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM/1.1 mm
90.	8065751079/ FE Lot # P1083560H	IIb	45150	20GA TOTALPLUS® Comb Proc Pak 5000CPM/0.9 mm
91.	8065751065/ FE Lot # P1083559H	IIb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM/1.1 mm
92.	8065751077/ FE Lot # P1083557H	IIb	45150	23GA TOTALPLUS® Comb Proc Pak 5000CPM/0.9 mm
93.	8065751466/ FE Lot # P1083556H	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM/1.1 mm
94.	8065751468/ FE Lot # P1083555H	IIb	45150	25+™ TOTALPLUS® Comb Proc Pak 5000CPM/0.9 mm

Title: DOC,MDD,CONSTELLATION CONS	Drawing Number: 931-2380-001	Revision: G
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**Attachment to the
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FOR
Constellation® Consumables**

Item #	Catalog Number	MDD Class	GMDN Code	Item Description
Constellation® Accessories				
95.	8065750914	Ila	45150	Constellation® Infusion Tubing Set W/ Auto Infusion Valve
96.	8065750917	Ila	45150	Constellation® Aux Aspiration Line
97.	8065750918	Ila	45150	Constellation® Irrigation/Aspiration Tubing set
98.	8065750920	Ila	45150	Constellation® Admin Tubing Set (GFI)
99.	8065751163	I	47783	Constellation® Tray Arm Cover
100.	8065751706	Ila	45150	25Ga Sclerotomy/Infusion 3.2mm Set

Title: DOC,MDD,CONSTELLATION CONS	Drawing Number: 931-2380-001	Revision: G
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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 15, 2011

Supersedes Declaration Dated: June 2, 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® Consumables

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

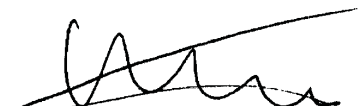
☐ **Article 12** [Check for systems (e.g. Kits) / Procedure Pack(s)]:
We have verified the (a) mutual compatibility of the devices in accordance with the manufacturer(s) instructions and carried out our operations in accordance with these instructions. We have (b) packaged the product and supplied relevant 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.


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Signed: 

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SIR&D Quality System Management Representative
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**Attachment to the
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FOR
Constellation[®] Consumables**

Item #	Catalog Number	MDD Class	GMDN Code	Item Description
1.	8065751162	I	11301	Constellation [®] Drain Bags (Non-Sterile)

Title: DOC,MDD,CONSTELLATION CONS	Drawing Number: 931-2380-001	Revision: G
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