

EC Declaration of Conformity**According to Directive 93/42/EEC as amended by 2007/47/EC**

Manufacturer Bausch & Lomb, Incorporated
1400 N. Goodman St.
Rochester, NY 14609 USA

European Authorized Representative(s)* Bausch & Lomb GmbH
Brunsbütteler Damm 165/173
13581 Berlin, Germany

Notified Body TUV Rheinland
LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Notified Body Number: 0197

EC Certificate Number EC Cert: HD 60146676 0001

Product (s) Stellaris Elite Procedure Packs

Product Code(s) See Table on Pages 2 and 3

GMDN Code 45150, 47130, 45074, 47424

Classification IIb Rule 11, according to Directive 93/42/EEC Annex IX

We hereby declare the conformity of the above mentioned products with the European Medical Device Directive 93/42/EEC as amended by 2007/47/EC Annex II, Section 3. Above product(s) is/are developed and manufactured in compliance with the MDD and the applicable European harmonized standards.

Place of Issue: Refer to Manufacturer's Address above

Signature: *Heather Christie* Date: June 9, 2021

Name/Title/Position: Heather Christie, Sr. Specialist, Regulatory Affairs

EC DECLARATION OF CONFORMITY

Manufacturer	Bausch & Lomb, Incorporated 1400 N. Goodman St. Rochester, NY 14609 USA
Product (s)	Stellaris Elite Procedure Packs

Item Number (SKU)	Product Name
Adaptive Fluidic Packs	
BL5115-1	Adaptive Fluidics Premium Pack
BL5115-2	Adaptive Fluidics Standard Pack
BL5115-3	Adaptive Fluidics MICS Premium Pack
BL5115-4	Adaptive Fluidics Basic Pack
Stellaris Elite Packs	
SE5420W	20 ga. Posterior Wide-Field Elite Pack
SE5423WV	23 ga. Posterior Wide-Field Elite Pack
SE5425WV	25 ga. Posterior Wide-Field Elite Pack
SE5420M	20 ga. Posterior Mid-Field Elite Pack
SE5423MV	23 ga. Posterior Mid-Field Elite Pack
SE5425MV	25 ga. Posterior Mid-Field Elite Pack
SE5520M	20 ga. Combined Mid-Field Elite Pack
SE5523MV	23 ga. Combined Mid-Field Elite Pack
SE5525MV	25 ga. Combined Mid-Field Elite Pack
SE5520W	20 ga. Combined Wide-Field Elite Pack
SE5523WV	23 ga. Combined Wide-Field Elite Pack
SE5525WV	25 ga. Combined Wide-Field Elite Pack
Stellaris Elite Packs with Bi-Blade Vitrectomy Cutters	
SE5423MVB	23 ga. Bi-Blade Vitreous Cutter Posterior Mid-Field Stellaris Elite Pack
SE5423WVB	23 ga. Bi-Blade Vitreous Cutter Posterior Wide-Field Stellaris Elite Pack
SE5523MVB	23 ga. Bi-Blade Vitreous Cutter Combined Mid-Field Stellaris Elite Pack
SE5523WVB	23 ga. Bi-Blade Vitreous Cutter Combined Wide-Field Stellaris Elite Pack
SE5425MVB	25 ga. Bi-Blade Vitreous Cutter Posterior Mid-Field Stellaris Elite Pack
SE5425WVB	25 ga. Bi-Blade Vitreous Cutter Posterior Wide-Field Stellaris Elite Pack
SE5525MVB	25 ga. Bi-Blade Vitreous Cutter Combined Mid-Field Stellaris Elite Pack
SE5525WVB	25 ga. Bi-Blade Vitreous Cutter Combined Wide-Field Stellaris Elite Pack
SE5427MVB	27 ga. Bi-Blade Vitreous Cutter Posterior Mid-Field Stellaris Elite Pack
SE5527MVB	27 ga. Bi-Blade Vitreous Cutter Combined Mid-Field Stellaris Elite Pack
SE5427WVB	27 ga. Bi-Blade Vitreous Cutter Posterior Wide-Field Stellaris Elite Pack
SE5527WVB	27 ga. Bi-Blade Vitreous Cutter Combined Wide-Field Stellaris Elite Pack

Item Number (SKU)	Product Name
7500 cuts per minute (cpm) Vitrectomy Cutters (pouched)	
BL5626	20 ga. Vitrectomy Cutter, 7500 cpm
BL5627	23 ga. Vitrectomy Cutter, 7500 cpm
BL5628	25 ga. Vitrectomy Cutter, 7500 cpm
SE5623	23 ga. Stellaris Elite Vitrectomy Probe (<i>RX version - 7500 cpm / alternate</i>)
SE5625	25 ga. Stellaris Elite Vitrectomy Probe (<i>RX version - 7500 cpm / alternate</i>)
7500 cuts per minute (cpm) Bi-Blade Vitrectomy Cutters (pouched)	
SE5623B	23 ga. Bi-Blade Vitrectomy Cutter, 7500 cpm
SE5625B	25 ga. Bi-Blade Vitrectomy Cutter, 7500 cpm
SE5627B	27 ga. Bi-Blade Vitrectomy Cutter, 7500 cpm
Anterior Vitrectomy (pouched) accessory kits	
SE5620AV	Stellaris Elite PC 20 GA Anterior Vitrectomy
SE5623AV	Stellaris Elite PC 23 GA Anterior Vitrectomy
Miscellaneous accessory component (pouched)	
BL3124S	2.4mm Sleeve for BL3318 and BL3420

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Product (s) Procedure Packs

Product Code(s) See Attached Table on Pages 2-5

GMDN Code 45150, 47130, 45074, 47424

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Place of Issue: Refer to Manufacturer's Address above

Signature: Ken Nehmer Date: Oct. 15, 2020

Name/Title/Position: Ken Nehmer, Director, Regulatory Affairs

* The previous EU Authorized Rep address may appear on product manufactured prior to 29-Mar-2019.
Bausch & Lomb, Incorporated
106 London Road
Kingston-upon-Thames
KT2 6TN UK

EC DECLARATION OF CONFORMITY

Manufacturer	Bausch & Lomb, Incorporated 1400 N. Goodman St. Rochester, NY 14609 USA
Product (s)	Procedure Packs

Item Number (SKU)	Product Name
BL3118	MICS 1.8 mm phaco needle sleeve
BL3190	Vitrectomy Adapor Kit
BL3318	MICS 1.8 Phaco Needle, Straight
BL3318A	MICS 1.8 Phaco Needle Angled
BL3318S	MICS 1.8 Phaco Needle
BL3318AS	MICS 1.8 Phaco Needle Angled
BL3394	Vitrectomy Handle Extension
BL3420	MICS Needle, Reusable
BL3420A	MICS Needle, Angled, Reusable
BL3420AS	MICS 2.0 Phaco Needle Angled
BL3420S	MICS 2.0 Phaco Needle
BL5110	Premium Vacuum Phaco Pack
BL5111	Basic Vacuum Phaco Pack
BL5112	Optimized stability Vacuum Pack
BL5113	1.8 mm Stable Chamber Phaco Pack
BL5113A	1.8 mm Stable Chamber Phaco Pack, angled
BL5114	Premium phaco pack 1.8 mm ST
BL5114A	Premium phaco pack 1.8 mm ANG
BL5200	Posterior Basic Pack
BL5220W	20 Ga Posterior Vitrectomy Pack With Wide Field Illuminator
BL5220WX	20ga Post Vitrectomy Pack W/ WFI
BL5223V	23G Gapost PK W. V&FF
BL5223W	23g Post. Vitrectomy
BL5223WV	23G Gapost PK W. V&WF
BL5223WVX	23ga Posterior Vitrectomy Pack W/ Valves And Wfi
BL5225V	25G Gapost PK W. V&FF
BL5225W	25g Post. Vitrectomy
BL5225WV	25G Gapost PK W. V&WF
BL5225WVX	25ga Posterior Vitrectomy Pack W/ Valves And Wfi
BL5275	Frag Needle
BL5277	23GA Angled Fragmentation Needles
BL5280	Stellaris PC Dual Infusion Kit
BL5300	Combined Basic Pack
BL5320W	20G Combined Procedure Pack
BL5320WX	20g Comb Vitrectomy Pack W/ WFI
BL5323WV	23G Gapost PK W. V&WF
BL5323WVX	23ga Combined Vitrectomy Pack W/ Valves And WFI
BL5325WV	25G Gapost PK W. V&WF
BL5325WVX	25ga Combined Vitrectomy Pack W/ Valves And WFI

Item Number (SKU)	Product Name
BL5400	Posterior with AFI Basic Pack
BL5420W	20GA Posterior Vitrectomy Pack With AFI And Wide Field
BL5420WX	20ga Posterior Vitrectomy Pack W/ AFI And WFI
BL5423WV	23G Gapost PK W. V&WF
BL5423WVX	23ga Posterior Vitrectomy Pack W/ Valves And AFI And WFI
BL5425V	25G Gapost PK W. V&FF
BL5425WV	25G Gapost PK W. V&WF
BL5425WVX	25ga Posterior Vitrectomy Pack W/ Valves And AFI And WFI
BL5500	Combined with AFI Basic Pack
BL5520W	20GA Combined Vitrectomy Pack With AFI And Wide Field
BL5520WX	20ga Combined Vitrectomy Pack W/ AFI And WFI
BL5523WV	23G Gapost PK W. V&WF
BL5523WVX	23ga Combined Vitrectomy Pack W/ Valves And AFI And WFI
BL5525WV	25G Gapost PK W. V&WF
BL5525WVX	25ga Combined Vitrectomy Pack W/ Valves And AFI And WFI
BL5427MVXB	27G Bi-Blade® Vitreous Cutter Posterior Mid-Field Stellaris PC Pack
BL5527MVXB	27G Bi-Blade® Vitreous Cutter Combined Mid-Field Stellaris PC Pack
BL5612	20g Anterior Vitrectomy
BL5620	20g High Speed Pneu Vit Cutter
BL5623	23g High Speed Pneu Vit Cutter
BL5623S	23G Stellaris PC Vitrectomy Probe
BL5625	25g High Speed Pneu Vit Cutter
BL5625S	25G Stellaris PC Vitrectomy Probe
BLP226MX30	Sterile kit with MICS needle and Thin Tip sleeves, needle wrench, stop, and test chamber (2.4-2.6mm) + 30 deg. Needle orifice
BLP324MX30	Sterile kit with MICS needle and green sleeves, needle wrench, stop, and test chamber (2.2-2.4mm) + 30 deg. Needle orifice
BLP6000000	Remote drape pouch
BLS0000000	StableChamber tubing only pack (cassette, tubing, screen drape, tray drape)
BLS226TT30	2.4-2.6mm Integrated StableChamber Pack with Thin Tip needle and green sleeves and 2 drapes + 30 deg. Needle orifice
BLV0000000	Vacuum-tubing only pack (cassette, tubing, screen drape, tray drape)
BLV126MF30	2.6-2.8mm Integrated vacuum Pack containing MicroFlow needle and standard sleeves and 2 drapes+ 30 deg. Needle orifice
BLV128MP30	2.8-3.0mm Integrated Vacuum Pack containing MicroFlow

Item Number (SKU)	Product Name
	Plus needle and standard sleeves and 2 drapes + 30 deg. Needle orifice
BLV2260000	2.6-2.8mm Vacuum Pack containing Thin Tip sleeves, 2 drapes but no needle
BLV3220000	2.2 to 2.4mm Vaccum Pack containing green sleeves, 2 drapes but no needle
BLV322MM30	2.2-2.4mm Integrated vacuum pack with MM(MicroFlow MICs) needle and green sleeves and 2 drapes + 30 deg. Needle orifice
BLV4180000	1.8-2.0mm Vacuum Pack containing MICS sleeves, 2 drapes but no needle
D8109	Infusion Sleeve, Standard II
D4600A	Air Exchange Line Pack
DP5501	Millenium / Premier
DP5511	Needle Sleeve
DP5531	Needle Sleeve
DP8030S	1 Needle Microseal 30 Degree Sterile
DP8130	Standard 30° Needle
DP8130S	Standard 30° Needle
DP8145	Standard 45° Needle
DP8145S	Standard 45° Needle
DP8215	Microflow Phaco Needle 15 Deg
DP8230	Microflow 30° Needle
DP8230A	Microflow Plus Ang 30 Deg.
DP8230S	Microflow.NDL.30 Deg.Ster.6/B, Sterile
DP8245	Needle Microflow 45 Deg.
DP8245S	Microflow 45° Needle
DP8300	Microflow Plus Ndl 0 Deg 6/Box
DP8315	Needle Microflow Plus 15 Deg
DP8330	Needle Microflow Plus 30°
DP8330A	Microflow Plus Ang 30 Deg
DP8330S	Microflow Plus 30° Needle
DP8345	Microflow Plus 45° Needle
DP8415	Thin Tip 15° Needle
DP8430	Thin Tip 30° Needle
DP8430AS	Phaco needle pack, DP8430AS, angled thin tip
DP8430S	Phaco Needle Pack DP8430S 6/B, sterile Thin tip
DP8730	Needle, Microflow 2.2
DP8730S	Microflow 2.2 30° Needle
DP8830AS	Vortex 19/20g 30° Angled Needle
DP8830S	Vortex 19/20g 30° Needle
DP8930AS	Vortex 20/21g 30° Angled Needle
DP8930S	Vortex 20/21g 30° Needle
MVS 1600A	Reusable Frag Needle 15°
MVS 1601A	Reusable Frag Needle 30°
MVS3201-6	Ant/Vit Probe 6/box