BAUSCH + LOMB

1400 North Goodman Street
Rochester, NY 14609
585.338.6000
www.bausch.com

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 Tillystraβe 2 90431 Nürnberg Notified Body Number: 0197
EC Certificate Number	EC Cert: HD 60105024 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: Ken Nehmer Date: Aug. 16, 2019

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

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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	
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
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 *(RX version - 7500 cpm / alternate)*
SE5625	25 ga. Stellaris Elite Vitrectomy Probe *(RX version - 7500 cpm / alternate)*

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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
Item Number (SKU)	**Product Name**
Miscellaneous accessory component (pouched)	
BL3124S	2.4mm Sleeve for BL3318 and BL3420