

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

Bausch & Lomb GmbH

Representative(s)*

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 60146676 0001

Product (s)

Dk-line Perfluoro-decalin Liquid Okta-line Perfluoro-octane Liquid

Product Code(s)

See Attached Table on Page 2

Classification

IIa, Rule 7, 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:

Date: 1-19-2021

Name/Title/Position:

Dan Regan, Senior Director Regulatory Affairs,

Surgical Equipment & Devices

^{*} 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	
300 CASCOLO CON PRODUCTION STOCKED STO	1400 N. Goodman St.	
	Rochester, NY 14609 USA	
Product (s)	Dk-line Perfluoro-decalin Liquid	
	Okta-line Perfluoro-octane Liquid	

Item Number (SKU)	Product Name
VRL100	Dk-line Perfluoro-decalin Liquid
VRL110	Dk-line Perfluoro-decalin Liquid
VRL200	Okta-line Perfluoro-octane Liquid