

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 60105024 0001

Product (s) Silicone Oil

Product Code(s) Oxane 1300 10 ml syringe
Oxane 5700 10 ml syringe
Oxane Hd 10 ml syringe

GMDN Code 45125

Classification IIb, Rule 8, 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: E. A. Desai Date: October 23, 2018

Name/Title/Position: Esha Desai, Senior Manager, 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)	Silicone Oil

Item Number (SKU)	Product Name
VRL500	Oxane 1300 10 ml syringe
VRL600	Oxane 5700 10 ml syringe
VRL700	Oxane Hd 10 ml syringe