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 Tillystraße 2 90431 Nürnberg Notified Body Number: 0197
EC Certificate Number	EC Cert: HD 60105024 0001
Product (s)	Amvisc / Amvisc Plus
Product Code(s)	See Attached Table on Page 2
GMDN Code	35907
Classification	IIb, Rule 6, 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: Sue Sutton-Jones Date: 21 March 2019

Name/Title/Position: Sue Sutton-Jones, Associate 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

Revision: R

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EC DECLARATION OF CONFORMITY

Manufacturer	Bausch & Lomb, Incorporated 1400 N. Goodman St. Rochester, NY 14609 USA
Product (s)	Amvisc/Amvisc Plus

Item Number (SKU)	Product Name
59081L	Amvisc, 0.8 mL
60081L	Amvisc Plus, 0.8 mL

Revision: R