

EC Declaration of Conformity

According to Directive 93/42/EEC as amended by 2007/47/EC

Legal Manufacturer Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609
U.S.A.

European Authorized Representative(s)* Bausch & Lomb Incorporated
Cork Road Industrial Estate
Waterford, X91 V383, Ireland

Notified Body National Standards Authority of Ireland (NSAI)
1 Swift Square
Northwood, Santry
Dublin 9, Ireland
Notified Body number: 0050

EC Certificate Number 252.332

Product (s) Soft Corrective Contact Lens, Extended-Wear, Therapeutic
Contact Lens (balafilcon A)

GMDN Code 47843, 36054

Classification Class IIa, Rule 5, 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 Legal Manufacturer's Address above

Signature: Nancy A. Fehrman Date: June 11, 2020

Name/Title/Position: Nancy Fehrman, Senior Manager, Regulatory Affairs

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

EC DECLARATION OF CONFORMITY
According to Directive 93/42/EEC as amended by 2007/47/EC

Legal Manufacturer	Bausch & Lomb Incorporated 1400 North Goodman Street Rochester, NY 14609 U.S.A.
Product (s)	Soft Corrective Contact Lens, Extended-Wear, Therapeutic Contact Lens (balafilcon A)
Product Name	
Bausch & Lomb PureVision	
Bausch & Lomb PureVision Toric	
Bausch & Lomb PureVision Multi-Focal	
Bausch & Lomb PureVision2	
Bausch + Lomb PureVision	
Bausch + Lomb PureVision Toric	
Bausch + Lomb PureVision Multi-Focal	
Bausch + Lomb PureVision2	
Bausch + Lomb PureVision2 for Astigmatism	
Bausch + Lomb PureVision2 for Presbyopia	
See Attachment 1 for Private Label Names	