EC Declaration of Conformity

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

Bausch & Lomb Incorporated

Legal Manufacturer 1400 North Goodman Street

Rochester, NY 14609

U.S.A.

European Authorized Representative(s)*

Notified Body

Bausch & Lomb Incorporated Cork Road Industrial Estate Waterford, X91 V383, Ireland

National Standards Authority of Ireland (NSAI)

1 Swift Square Northwood, Santry

Dublin 9, Ireland

Notified Body number: 0050

EC Certificate Number 252.139

Product (s) Soft Contact Lenses, daily-wear and extended wear

(polymacon)

GMDN Code 47842 47843

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

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Name/Title/Position:

Nancy Fehrman, Senior Manager, Regulatory Affairs

Janua A Johnson Date: Sont. 11, 7000

*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

Signature:



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 Contact Lenses, daily-wear and extended wear (polymacon)

Product Name			
Daily Wear (GMDN Code 47842):			
SofLens Multifocal			
OPTIMA 38/SP			
OPTIMA 38			
SofLens Natural Colors			
SofLens Starcolors II			
Optima Natural Look			
MAXSIGHT			
OPTIMA 6M			
SofLens 38			
Bausch & Lomb Primalents			
HO3			
HO4			
H3			
H4			
B3			
F			
F3			
N			
Plano T			
SofSpin II			
Waicon Tri-Kolor (excluding plano* contact lenses)			
Waicon Tri-Kolor-XS (excluding plano* contact lenses)			
Waicon Basic Colours (excluding plano* contact lenses)			
Basic Colours (excluding plano* contact lenses)			
Basic Colours XS (excluding plano* contact lenses)			
Amazon (excluding plano* contact lenses)			
Amazon XS (excluding plano* contact lenses)			
Lumina (excluding plano* contact lenses)			
Lunare (excluding plano* contact lenses)			
Lune (excluding plano* contact lenses)			
_umen (excluding plano* contact lenses)			
Soflens Starcolors III (excluding plano* contact lenses)			
Aquarelle (excluding plano* contact lenses)			
*Plano contact lenses have no optical power (0.00 Diopters)			

Product Name		
Extended Wear (GMDN Code 47843):		
OPTIMA FW / 47843		
SofLens 38 / 47843		
SeeQuence / 47843		
See Attachment 1 for Private Label Names		

Revision: P