

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 252.139

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

Signature:

Nancy A. Fehrman Date: Sept. 11, 2010

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 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
Wacon Tri-Kolor (excluding plano* contact lenses)
Wacon Tri-Kolor-XS (excluding plano* contact lenses)
Wacon 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)
Lumen (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