1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

BAUSCH & LOMB INCORPORATED
DECLARATION OF CONFORMITY

Bausch & Lomb Incorporated declares under its sole responsibility that the product(s) listed are made in accordance with the Essential Requirements of the European Economic Community Medical Device Directive, ANNEX II [EC93/42/EEC].

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

Medical Device: Soft Contact Lenses, daily-wear and extended wear (polymacon)

File Number: 252.139

Products / GMDN Code:
SofLens Multifocal / 47842
OPTIMA 38/SP / 47842
OPTIMA 38 / 47842
SofLens Natural Colors / 47842
Soflens Starcolors II / 47842
Optima Natural Look / 47842
MAXSIGHT / 47842
OPTIMA FW / 47843
OPTIMA 6M / 47842
SofLens 38 / 47842
SofLens 38 / 47843
Bausch & Lomb Primalents / 47842
HO3 / 47842
HO4 / 47842
H3/ 47842
H4 / 47842
B3 / 47842
F / 47842
F3 / 47842
N / 47842
Plano T / 47842
SofSpin II/ 47842
SeeQuence / 47843
Waicon Tri-Kolor/ 47842 (excluding plano* contact lenses)
Waicon Tri-Kolor-XS/ 47842 (excluding plano* contact lenses)
Waicon Basic Colours/ 47842 (excluding plano* contact lenses)

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Basic Colours/ 47842 (excluding plano* contact lenses)
Basic Colours XS/ 47842 (excluding plano* contact lenses)
Amazon/ 47842 (excluding plano* contact lenses)
Amazon XS/ 47842 (excluding plano* contact lenses)
Lumina/ 47842 (excluding plano* contact lenses)
Lunare/ 47842 (excluding plano* contact lenses)
Lune/ 47842 (excluding plano* contact lenses)
Lumen/ 47842 (excluding plano* contact lenses)
Soflens Starcolors III/ 47842 (excluding plano* contact lenses)
Aquarelle/ 47842 (excluding plano* contact lenses)

*Plano contact lenses have no optical power (0.00 Diopters)

Device Class:
Class IIa, Rule 5

Quality Management System Certificate:
Bausch & Lomb Incorporated (Rochester): NSAI MD19.1854
1400 North Goodman Street
Rochester, NY 14609
USA

Bausch & Lomb Ireland: NSAI MD19.1854/E
Unit 424/425 Contact Lens Division
Industrial Estate
Cork Road
Waterford
Ireland

B.L. Industria Otica Ltda.: NSAI MD19.1858
Rua Dona Alzira 139
Porto Alegre RS
91110-010 Brazil

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

*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 Surrey
KT2 6TN UK

BAUSCH + LOMB

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

The referenced product(s) conform to the following standards and / or other normative documents, pursuant to the provisions of the European Economic Community Medical Device Directive Regulations:

Standard	Title
EN 556-1:2001	Sterilization of Medical Devices – Requirements for Medical Devices to be Designated "Sterile" – Part 1: Requirements for Terminally Sterilized Medical Devices.
EN 1041:2008	Information Supplied by the Manufacturer for Medical Devices
EN ISO 10993	Biological Evaluation of Medical Devices Part 1: 2009 – Evaluation and testing within a risk management process Part 5: 2009 – Tests for In Vitro Cytotoxicity Part 10: 2010 – Tests for Irritation and Delayed Type Hypersensitivity Part 11: 2009 – Tests for Systemic Toxicity
EN ISO 11607	Part 1: 2009 - Packaging for Terminally Sterilized Medical Devices - Requirements for materials, sterile barrier systems and packaging systems Part 2: 2006 - Packaging for Terminally Sterilized Medical Devices - Validation requirements for forming, sealing and assembly processes
EN ISO 11978:2000	Contact Lenses and Contact Lens Care Products – Information Supplied by the Manufacturer
EN ISO 11981:2009	Ophthalmic Optics – Contact Lenses and Contact Lens Care Products – Determination of physical compatibility of contact lens care products with contact lenses
EN ISO 11987:2012	Optics and Optical Instruments – Contact Lenses – Determination of Shelf Life
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice - Second Edition
EN ISO 14534:2011	Ophthalmic Optics – Contact lenses and contact lens care products – Fundamental Requirements
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 17665-1:2006	Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 18369	Parts 1, 3-4: 2006 - Ophthalmic Optics – Contact Lenses Part 2 - Tolerances: 2012 - Ophthalmic Optics – Contact Lenses
EN ISO 62366:2008	Medical Devices - Application of usability engineering to medical devices

Signed on behalf of Bausch & Lomb Incorporated

Nancy A. Fehrman

Nancy Fehrman
Senior Manager, Regulatory Affairs

Oct. 17, 2018

Issuance Date

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
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BAUSCH & LOMB INCORPORATED
DECLARATION OF CONFORMITY

Bausch & Lomb Incorporated declares under its sole responsibility that the product(s) listed are made in accordance with the Essential Requirements of the European Economic Community Medical Device Directive, ANNEX II [EC93/42/EEC].

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

Medical Device: Multi-Purpose Rigid Contact Lens Solutions

File Number: 252.281

Products / GMDN Code:

Bausch & Lomb Elite Conditioning Solution / 48075
Bausch & Lomb Elite MultiPak / 48075
Bausch & Lomb RGP Conditioner / 48075
Bausch & Lomb Boston Advance Comfort Formula Conditioning Solution / 48075
Bausch & Lomb Simplus Multi-Action Solution HGP MPS / 48075
Boston Conditioning Solution / 48075
Boston Classic Conditioning Solution / 48075
Boston Conditioner (formula BCIII) / 48075
Boston ADVANCE Conditioner (formula BCIII) / 48075
Boston ADVANCE FORMULA Conditioner (formula BCIII) / 48075
Boston ADVANCE COMFORT FORMULA Conditioner (formula BCIII) / 48075
Boston Conditioner ADVANCE COMFORT FORMULA (formula BCIII) / 48075
Boston Conditioner ADVANCE (formula BCIII / 48075
Boston Conditioner ADVANCE FORMULA (formula BCIII) / 48075
Boston Conditioning Solution (formula BCIII) / 48075
Boston ADVANCE Conditioning Solution (formula BCIII) / 48075
Boston ADVANCE FORMULA Conditioning Solution (formula BCIII) / 48075
Boston ADVANCE COMFORT FORMULA Conditioning Solution (formula BCIII) / 48075
Boston Conditioning Solution ADVANCE COMFORT FORMULA (formula BCIII) / 48075
Boston Conditioning Solution ADVANCE (formula BCIII) / 48075
Boston Conditioning Solution ADVANCE FORMULA (formula BCIII) / 48075
Boston simplus 120 ml /48075
Boston Simplus Multi-action Solution/48075

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

See Attachment 1: Private Labelling

Device Class: Class IIb, Rule 15

Quality Management System Certificate:
Bausch & Lomb (Greenville): NSAI MD19.1854/A
Manufacturing Address:
8507 Pelham Road
Greenville, SC 29615
USA

Bausch & Lomb (Milan): NSAI MD19.1268

Registered office address:
Via Martesana, 12
20090 Vimodrone
Milano
Italy

Manufacturing Plant address:
Via Pasubio, 34
20846 Macherio
Monza e Brianza
Italy

European Authorized Representative*:
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

*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 Surrey
KT2 6TN UK

BAUSCH + LOMB

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

The referenced product(s) conform to the following standards and / or other normative documents, pursuant to the provisions of the European Economic Community Medical Device Directive Regulations:

Standard	Title
EN 1041:2008	Information Supplied by the Manufacturer for Medical Devices
EN ISO 10993	Biological Evaluation of Medical Devices Part 1: 2009 – Evaluation and testing within a risk management process Part 5: 2009 – Tests for In Vitro Cytotoxicity Part 10: 2010 – Tests for Irritation and Delayed Type Hypersensitivity Part 11: 2009 – Tests for Systemic Toxicity
EN ISO 11978:2000	Contact Lenses and Contact Lens Care Products – Information Supplied by the Manufacturer
EN ISO 13212:2011	Ophthalmic Optics – Contact Lens Care Products - Guidelines for Determination of Shelf Life
EN ISO 13408	Part 1: 2015 - Aseptic Processing of Health Care Products - General Requirements Part 2: 2011 - Aseptic Processing of Health Care Products - Filtration
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2009	Clinical investigation of medical devices for human subjects Part 1: General Requirements Part 2: Clinical Investigation Plans
EN ISO 14534:2011	Ophthalmic Optics – Contact lenses and contact lens care products – Fundamental Requirements
ISO 14729:2001	Ophthalmic Optics – Contact Lens Care Products - Microbiological Requirements and test methods for products and regimens for hygienic management of contact lenses (AMD 1 - 2010)
ISO 14730:2000	Ophthalmic Optics – Contact Lens Care Products - Antimicrobial Preservative Efficacy Testing and Guidance on Determining Discard Date
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 62366:2008	Medical Devices - Application of usability engineering to medical devices

Signed on behalf of Bausch & Lomb Incorporated,

Nancy A. Fehrman

Nancy Fehrman
Senior Manager, Regulatory Affairs

Sept. 18, 2019

Issuance Date

Quality System Approval Certificate
Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Bausch & Lomb Incorporated

1400 North Goodman Street
Rochester
NY 14609
USA

to the Product Family

Soft Corrective Contact Lens, Extended-wear, Therapeutic Contact Lens (balafilcon A)

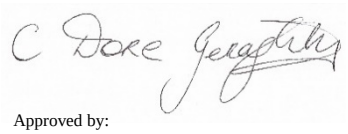
GMDN Code: 47843, 36054

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.332**
Original Approval:	**11 May 1998**
Last Amended on:	**3 March 2020**
Remains valid until:	**26 May 2024**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

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BAUSCH & LOMB INCORPORATED
DECLARATION OF CONFORMITY

Bausch & Lomb Incorporated declares under its sole responsibility that the product(s) listed are made in accordance with the Essential Requirements of the European Economic Community Medical Device Directive, ANNEX II [EC93/42/EEC].

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

Medical Device: Soft Corrective Contact Lens, Extended-wear, Therapeutic Contact Lens (balafilcon A)

File Number: 252.332

Products / GMDN Code:

Bausch & Lomb PureVision / 36054
Bausch & Lomb PureVision Toric / 36054
Bausch & Lomb PureVision Multi-Focal / 36054
Bausch & Lomb PureVision2 / 36054
Bausch + Lomb PureVision / 36054
Bausch + Lomb PureVision Toric / 36054
Bausch + Lomb PureVision Multi-Focal / 36054
Bausch + Lomb PureVision2 / 36054
Bausch + Lomb PureVision2 for Astigmatism/ 36054
Bausch + Lomb PureVision2 for Presbyopia/ 36054

Bausch & Lomb PureVision / 47843
Bausch & Lomb PureVision Toric / 47843
Bausch & Lomb PureVision Multi-Focal / 47843
Bausch & Lomb PureVision2 / 47843
Bausch + Lomb PureVision / 47843
Bausch + Lomb PureVision Toric / 47843
Bausch + Lomb PureVision Multi-Focal / 47843
Bausch + Lomb PureVision2 / 47843
Bausch + Lomb PureVision2 for Astigmatism / 47843
Bausch + Lomb PureVision2 for Presbyopia/ 47843

See Attachment 1 for Private Label names

1400 North Goodman Street
Rochester, NY 14609
585.338.6000
www.bausch.com

Device Class: Class IIa, Rule 5

Quality Management System Certificate:
Bausch & Lomb Incorporated (Rochester): NSAI MP19.1854/ Rev 1
1400 North Goodman Street
Rochester, NY 14609
USA

Bausch & Lomb Ireland: NSAI MP19.1854/E
Unit 424/425 Contact Lens Division
Industrial Estate
Cork Road
Waterford
Ireland

European Authorized Representative:
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

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585.338.6000
www.bausch.com

The referenced product(s) conform to the following standards and / or other normative documents, pursuant to the provisions of the European Economic Community Medical Device Directive Regulations:

Standard	Title
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EN ISO 11981:2009	Ophthalmic Optics – Contact Lenses and Contact Lens Care Products – Determination of physical compatibility of contact lens care products with contact lenses
EN ISO 11987:2012	Optics and Optical Instruments – Contact Lenses – Determination of Shelf Life
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice - Second Edition
EN ISO 14534:2011	Ophthalmic Optics – Contact lenses and contact lens care products – Fundamental Requirements
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 17665-1:2006	Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 18369	Parts 1, 3-4: 2006 - Ophthalmic Optics – Contact Lenses Part 2 - Tolerances: 2012 - Ophthalmic Optics – Contact Lenses
EN ISO 62366:2008	Medical Devices - Application of usability engineering to medical devices

Signed on behalf of Bausch & Lomb Incorporated

Nancy A. Fehrman
Nancy Fehrman
Senior Manager, Regulatory Affairs

Sept. 13, 2018
Issuance Date

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

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	252.347
Product (s)	Soft Corrective Contact Lens, Daily-Disposable and Daily Wear (hilafilcon)
GMDN Code	47841(Disposable)/4782 (Daily Wear)
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: May 21, 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

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

Legal Manufacturer	Bausch & Lomb Incorporated 1400 North Goodman Street Rochester, NY 14609 U.S.A.
Product (s)	Soft Corrective Contact Lens, Daily-Disposable and Daily Wear (hilafilcon)

Product Name
Disposable (GMDN Code 47841):
Bausch & Lomb SofLens daily disposable (hilafilcon B) Visibility Tinted Contact Lens
Bausch & Lomb SofLens daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lens
Bausch & Lomb Naturelle daily disposable (hilafilcon B) Cosmetically Tinted Contact Lens
Daily Wear (GMDN Code 47842):
Bausch & Lomb SofLens 59 (hilafilcon B) Visibility Tinted Contact Lenses
Bausch & Lomb SofLens 59 (hilafilcon B) Visibility Tinted Contact Lenses for Daily Wear
See Attachment 1 for Private Label Names

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

BAUSCH & LOMB INCORPORATED
DECLARATION OF CONFORMITY

Bausch & Lomb Incorporated declares under its sole responsibility that the product(s) listed are made in accordance with the Essential Requirements of the European Economic Community Medical Device Directive, ANNEX II [EC93/42/EEC].

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

Medical Device: Hydrogen Peroxide Contact Lens Care Systems

File Number: 252.857

Products / GMDN Code (Branded Product):
Bausch & Lomb EasySept® (Hydrogen Peroxide) / 45088
Bausch + Lomb ReNu EasySept® / 45088
Bausch + Lomb ReNu EasySept peroxide solution / 45088
Bausch + Lomb EasySept® / 45088

See Attachment 1 for private label tradenames.

Device Class: Class IIb, Rule 15

Quality Management System Certificate:
Bausch & Lomb (Greenville): NSAI MD19.1854/A and MD19.1854/B

Manufacturing and Sterilization Address:
8507 Pelham Road
Greenville, SC 29615
USA

Distribution Address:
130 Commerce Drive
Greenville, SC 29615
USA

Bausch & Lomb (Milan): NSAI MD19.1268

Registered Office Address:
Via Martesana, 12
20090 Vimodrone
Milano
Italy

Manufacturing Plant Address:
Via Pasubio, 34
20846 Macherio
Monza e Brianza
Italy

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

European Authorized Representative*:
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

*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 Surrey
KT2 6TN UK

BAUSCH + LOMB

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

The referenced product(s) conform to the following standards and / or other normative documents, pursuant to the provisions of the European Economic Community Medical Device Directive Regulations:

Standard	Title
EN 1041:2008	Information Supplied by the Manufacturer for Medical Devices
EN ISO 10993	Biological Evaluation of Medical Devices Part 1: 2009 – Evaluation and testing within a risk management process Part 5: 2009 – Tests for In Vitro Cytotoxicity Part 10: 2010 – Tests for Irritation and Delayed Type Hypersensitivity Part 11: 2009 – Tests for Systemic Toxicity
EN ISO 11978:2000	Contact Lenses and Contact Lens Care Products – Information Supplied by the Manufacturer
EN ISO 13212:2014	Ophthalmic Optics – Contact Lens Care Products - Guidelines for Determination of Shelf Life
EN ISO 13408	Part 1: 2011 - Aseptic Processing of Health Care Products - General Requirements Part 2: 2011 - Aseptic Processing of Health Care Products - Filtration
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice - Second Edition
EN ISO 14534:2011	Ophthalmic Optics – Contact lenses and contact lens care products – Fundamental Requirements
EN ISO 14729:2001	Ophthalmic Optics – Contact Lens Care Products - Microbiological Requirements and test methods for products and regimens for hygienic management of contact lenses (AMD 1 - 2010)
EN ISO 14730:2014	Ophthalmic Optics – Contact Lens Care Products - Antimicrobial Preservative Efficacy Testing and Guidance on Determining Discard Date
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 62366:2008	Medical Devices - Application of usability engineering to medical devices

Signed on behalf of Bausch & Lomb Incorporated

Nancy A. Fehrman

Nancy Fehrman
Senior Manager, Regulatory Affairs

Feb. 15, 2019

Issuance Date

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

BAUSCH & LOMB INCORPORATED
DECLARATION OF CONFORMITY

Bausch & Lomb Incorporated declares under its sole responsibility that the product(s) listed are made in accordance with the Essential Requirements of the European Economic Community Medical Device Directive, ANNEX II [EC93/42/EEC].

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

Medical Device: Soft corrective contact lens, daily-disposable (nesofilcon A)
File Number: 252.860

Products / GMDN Code:

BAUSCH + LOMB Biotrue ONEday (nesofilcon A) Contact Lenses / 47841
BAUSCH + LOMB Biotrue ONEday (nesofilcon A) For Presbyopia Contact Lenses / 47841
BAUSCH + LOMB Biotrue ONEday (nesofilcon A) For Astigmatism Contact Lenses / 47841

See Attachment 1 for Private Label names

Device Class: Class IIa, Rule 5

Quality Management System Certificate:
Bausch & Lomb Ireland: NSAI MD19.1854/E
Unit 424/425 Contact Lens Division
Industrial Estate
Cork Road
Waterford, Ireland

European Authorized Representative:
Bausch & Lomb Incorporated
Cork Road Industrial Estate
Waterford, X91 V383, Irelalnd

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

BAUSCH + LOMB

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

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Standard	Title
EN 556-1:2001/AC 2006	Sterilization of Medical Devices – Requirements for Medical Devices to be Designated "Sterile" – Part 1: Requirements for Terminally Sterilized Medical Devices.
EN 1041:2008	Information Supplied by the Manufacturer for Medical Devices
EN ISO 10993	Biological Evaluation of Medical Devices Part 1: 2009/AC 2010– Evaluation and testing within a risk management process Part 5: 2009 – Tests for In Vitro Cytotoxicity Part 10: 2013 – Tests for Irritation and Delayed Type Hypersensitivity Part 11: 2009 – Tests for Systemic Toxicity
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EN ISO 11987:2012	Optics and Optical Instruments – Contact Lenses – Determination of Shelf Life
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice - Second Edition
EN ISO 14534:2011	Ophthalmic Optics – Contact lenses and contact lens care products – Fundamental Requirements
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 17665-1:2006	Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 18369	Parts 1, 3-4: 2006 - Ophthalmic Optics – Contact Lenses Part 2 - Tolerances: 2012 - Ophthalmic Optics – Contact Lenses
EN ISO 62366:2008	Medical Devices - Application of usability engineering to medical devices

Signed on behalf of Bausch & Lomb Incorporated,

Nancy A. Fehrman

Nancy Fehrman
Senior Manager, Regulatory Affairs

Oct. 5, 2018
Issuance Date

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1400 North Goodman Street
Rochester, NY 14609
585.338.6000
www.bausch.com

BAUSCH & LOMB INCORPORATED
DECLARATION OF CONFORMITY

Bausch & Lomb Incorporated declares under its sole responsibility that the product(s) listed are made in accordance with the Essential Requirements of the European Economic Community Medical Device Directive, ANNEX II [EC93/42/EEC].

Medical Device: Soft corrective Contact Lens, daily wear (Samfilcon A)

File Number: 252.913

Device Class: Class IIa

GMDN Code: 47842 Soft corrective contact lens, daily wear
47841 Soft corrective contact lens, daily-disposable

Products: BAUSCH + LOMB ProComfort™ (samfilcon A) Contact Lens
BAUSCH + LOMB ProComfort™ for Astigmatism (samfilcon A) Contact Lens
BAUSCH + LOMB ProComfort™ for Presbyopia (samfilcon A) Contact Lens
BAUSCH + LOMB Ultra (samfilcon A) Contact Lens
BAUSCH + LOMB Ultra for Astigmatism (samfilcon A) Contact Lens
BAUSCH + LOMB Ultra for Presbyopia (samfilcon A) Contact Lens

Manufacturer:
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609, USA

European Authorized Representative:
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

Quality Management System Certificate:
Bausch & Lomb Incorporated (Rochester): NSAI MP19.1854/ Rev 1

BAUSCH + LOMB
See better. Live better.

1400 North Goodman Street
Rochester, NY 14609
585.338.6000
www.bausch.com

The referenced product(s) conform to the following standards and / or other normative documents, pursuant to the provisions of the European Economic Community Medical Device Directive Regulations:

Standard	Title
EN ISO 13485:2016	Medical devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14155:2011	Clinical Investigation of Medical Devices For Human Subjects – Good Clinical Practice
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 14534:2011	Ophthalmic Optics – Contact lenses and contact lens care products – Fundamental Requirements
EN ISO 18369:2006	Ophthalmic Optics – Contact Lenses, Parts 1-4
EN ISO 11987:2012	Optics and Optical Instruments – Contact Lenses – Determination of Shelf Life
EN ISO 11981:2009	Ophthalmic Optics – Contact Lenses and Contact Lens Care Products – Determination of physical compatibility of contact lens care products with contact lenses
EN ISO 11978:2000	Contact Lenses and Contact Lens Care Products – Information Supplied by the Manufacturer
EN ISO 10993	Biological Evaluation of Medical Devices Part 1:2009 - Evaluation and testing within a risk management process Part 5:2009 – Tests for In Vitro Cytotoxicity Part 10:2010 – Tests for Irritation and Delayed Type Hypersensitivity Part 11:2009 – Tests for Systemic Toxicity
EN ISO 17665-1:2006	Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 556-1:2001	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
ISO 15223-1:2016	Graphical symbols for use in the labeling of medical devices
EN 1041:2008	Information Supplied by the Manufacturer for Medical Devices
EN ISO 11607	Packaging for terminally sterilized medical devices Part 1:2009 - Requirements for materials, sterile barrier systems and packaging systems Part 2:2006 - Validation requirements for forming, sealing and assembly processes

Signed on behalf of Bausch & Lomb Incorporated

Nancy A. Fehrman

Nancy Fehrman
Senior Manager, Regulatory Affairs

Oct. 10, 2018

Issuance Date

BAUSCH + LOMB

EG-KONFORMITÄTSERKLÄRUNG

gemäß Richtlinie 93/42/EWG über Medizinprodukte

EC DECLARATION OF CONFORMITY

according to Directive 93/42/EEC concerning Medical Devices

Wir:

Dr. Gerhard Mann chem.-pharm. Fabrik GmbH
Brunsbütteler Damm 165/173
13581 Berlin
Deutschland

erklären in alleiniger Verantwortung, dass das Medizinprodukt mit den Produktnamen laut der Anlage **Produkt Nr. 931** allen anwendbaren Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.

Risikoklasse: II b
Klassifizierungsregel: 5 & 15
Konformitätsbewertungsverfahren:
Anhang II – ohne Abschnitt 4

Beteiligte Benannte Stelle:

mdc medical device certification GmbH;
Kriegerstraße 6; D-70191 Stuttgart
Kennnummer 0483

We:

Dr. Gerhard Mann chem.-pharm. Fabrik GmbH
Brunsbütteler Damm 165/173
13581 Berlin
Germany

*declare under our sole responsibility that the Medical Device with the product names according to the annex **Product No. 931** meets all applicable requirements of the Directive 93/42/EEC concerning Medical Devices*

Risk class: II b
Classification rule: 5 & 15
Conformity assessment procedure:
Annex II – excluding Section 4

Involved Notified Body:

mdc medical device certification GmbH;
Kriegerstrasse 6; D-70191 Stuttgart
Identification No. 0483

Berlin, 06.03.2020
DATUM / *DATE*

DR. MAIKE NOLLEN-WITT,
REGULATORY AFFAIRS MANAGER FOR MEDICAL DEVICES
NAME UND FUNKTION/
NAME AND FUNCTION

RECHTSVERBINDLICHE UNTERSCHRIFT /
LEGALLY BINDING SIGNATURE

GÜLTIGKEITSDAUER / VALIDITY: 2023-02-19

ZERTIFIKATSNUMMER / CERTIFICATE NUMBER: D1016700022

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chem.-pharm. Fabrik GmbH
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www.bausch.com

Geschäftsführer
Eberhard Kühne
William Woodfield

Amtsgericht
Charlottenburg
HRB 25425
St.-Nr. 37/004/49749
USt-IdNr. DE13 6572 946

Citibank Europe plc, Germany branch
BLZ 502 109 00
Kto.-Nr. 214 113 007
SWIFT CITIDEFF
IBAN DE54 5021 0900 0214 1130 07

BAUSCH+LOMB

Anlage **Produkt Nr. 931**
LISTE DER PRODUKTNAMEN:

Artelac Splash Eye Drops
Artelac Splash MDO
Aqualarm U.P. intensive
Artelac Splash MDSC
Artelac Splash MULTIDOSIS
Biotrue MDO
Hyal-Drop Advanced
Hyal-Drop ADVANCED
Biotrue Eye drops
Biotrue rewetting drops
Артелак Всплеск (Artelac Splash)
Dry &Irritated Eyes Preservative Free Eye Drops
Biotrue Soluzione oftalmica
Biotrue gotas hidratantes
Biotrue gotas oculares
Artelac Everyday

GMDN Code: 44237
Eine sterile Substanz, die das natürliche Auge zusätzlich befeuchtet, um trockene, müde und / oder angespannte Augen zu behandeln, die aus dem Syndrom des trockenen Auges (einer Störung, die zu trockenen, brennenden Symptomen und Fremdkörpergefühl führt), Alterung / Hormonveränderungen (Wechseljahre) resultieren. oder Umweltfaktoren (z. B. Medikamente, Umweltverschmutzung, Computernutzung, Klimaanlage und Kontaktlinsengebrauch). Es kann eine topische Lösung, ein Spray, eine Suspension oder ein Gel sein, das auf die Augen oder Augenlider aufgetragen wird, und kann spezielle Formulierungen aufweisen (z. B. intensive Verwendung bei Nacht). Es ist normalerweise rezeptfrei (OTC) für den Heimgebrauch (Einzeldosis oder Mehrfachdosis) erhältlich. Nach der Anwendung kann dieses Produkt nicht mehr verwendet werden.

Appendix ***Product No. 931***
LIST OF PRODUCT NAMES:

Artelac Splash Eye Drops
Artelac Splash MDO
Aqualarm U.P. intensive
Artelac Splash MDSC
Artelac Splash MULTIDOSIS
Biotrue MDO
Hyal-Drop Advanced
Hyal-Drop ADVANCED
Biotrue Eye drops
Biotrue rewetting drops
Артелак Всплеск (Artelac Splash)
Dry &Irritated Eyes Preservative Free Eye Drops
Biotrue Soluzione oftalmica
Biotrue gotas hidratantes
Biotrue gotas oculares
Artelac Everyday

GMDN code: 44237
A sterile substance intended to provide supplemental lubrication/hydration to the natural eye to treat dry, tired, and/or strained eyes resulting from dry eye syndrome (a disorder resulting in dry, gritty, burning symptoms), ageing/hormone changes (menopause), or environmental factors (e.g., medications, pollution, computer use, air conditioning, and contact lens use). It may be a topical solution, spray, suspension, or gel applied to the eyes or eyelids, and may have special formulations (e.g., intensive, night use). It is normally available [non-prescription] over-the-counter (OTC) for home-use (single dose or multidose). After application, this device cannot be reused.

06.03.2020

NBF 0036 08/19

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Geschäftsführer
Eberhard Kühne
William Woodfield

Amtsgericht
Charlottenburg
HRB 25425
St.-Nr. 37/004/49749
USt-IdNr. DE13 6572 946

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Kto.-Nr. 214 113 007
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IBAN DE54 5021 0900 0214 1130 07

BAUSCH + LOMB

EG-KONFORMITÄTSERKLÄRUNG

gemäß Verordnung 2017/745 über Medizinprodukte

EC DECLARATION OF CONFORMITY

according to Regulation 2017/745 concerning Medical Devices

Wir:

Dr. Gerhard Mann chem.-pharm. Fabrik GmbH
Brunsbütteler Damm 165/173
13581 Berlin
Deutschland
SRN: DE-MF-000006823

erklären in alleiniger Verantwortung, dass das Medizinprodukt mit den Produktnamen laut der Anlage **Produkt Nr. 931** allen anwendbaren Anforderungen Verordnung 2017/745 über Medizinprodukte entspricht.

Basis UDI: 4030571B09318D
Risikoklasse: IIb
Klassifizierungsregel: 21
Konformitätsbewertungsverfahren:
Anhang IX Kapitel I

Beteiligte Benannte Stelle:

mdc medical device certification GmbH;
Kriegerstraße 6; D-70191 Stuttgart
Kennnummer 0483

We:

Dr. Gerhard Mann chem.-pharm. Fabrik GmbH
Brunsbütteler Damm 165/173
13581 Berlin
Germany
SRN: DE-MF-000006823

*declare under our sole responsibility that the Medical Device with the product names according to the annex **Product No. 931** meets all applicable requirements of the Regulation 2017/745 concerning Medical Devices*

Basic UDI: 4030571B09318D
Risk class: IIb
Classification rule: 21
Conformity assessment procedure:
Annex IX chapter I

Involved Notified Body:

mdc medical device certification GmbH;
Kriegerstrasse 6; D-70191 Stuttgart
Identification No. 0483

Berlin, 15. FEB. 2023
DATUM / *DATE*

PETRIK DAUER
GENERAL MANAGER & COMMERCIAL DIRECTOR PHARMA DACH
NAME UND FUNKTION/
NAME AND FUNCTION

RECHTSVERBINDLICHE UNTERSCHRIFT /
LEGALLY BINDING SIGNATURE

MARKO STOTTMEYER / HEAD OF FINANCE DACH
NAME UND FUNKTION/
NAME AND FUNCTION

RECHTSVERBINDLICHE UNTERSCHRIFT /
LEGALLY BINDING SIGNATURE AND FUNCTION

GÜLTIGKEITSDAUER / VALIDITY: 2027-07-20

ZERTIFIKATSNUMMER / CERTIFICATE NUMBER: D1016700036

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chem.-pharm. Fabrik GmbH
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Geschäftsführer
Eberhard Kühne
Manoj Kumar Panda

Amtsgericht
Charlottenburg
HRB 25425
St.-Nr. 37/004/49749
USt-IdNr. DE13 6572 946

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IBAN DE 54 5021 0900 0214 1130 07

BAUSCH + LOMB

Anlage **Produkt Nr. 931**

*Appendix **Product No. 931***

Liste der Produktnamen

Artelac Splash Eye Drops
Artelac Splash MDO
Aqualarm U.P. intensive
Artelac Splash MDSC
Artelac Splash MULTIDOSIS
Artelac Splash MULTIDOSE
Biotrue MDO
Hyal Drop Advanced
Hyal-Drop ADVANCED
Biotrue Eye drops
Biotrue rewetting drops
Артелак Всплеск (Artelac Splash)
Dry & Irritated Eyes Preservative Free Eye Drops
Biotrue Soluzione oftalmica
Biotrue Gotas Hidratantes
Artelac Everyday
Hya-Ophtal system
Biotrue Eye Drops MDO
Hyal-Drop multi
Aqualarm U.P. intensive (0.24% sodium hyaluronate)
Biotrue Göz Damlası

List of product names

Artelac Splash Eye Drops
Artelac Splash MDO
Aqualarm U.P. intensive
Artelac Splash MDSC
Artelac Splash MULTIDOSIS
Artelac Splash MULTIDOSE
Biotrue MDO
Hyal Drop Advanced
Hyal-Drop ADVANCED
Biotrue Eye drops
Biotrue rewetting drops
Артелак Всплеск (Artelac Splash)
Dry & Irritated Eyes Preservative Free Eye Drops
Biotrue Soluzione oftalmica
Biotrue Gotas Hidratantes
Artelac Everyday
Hya-Ophtal system
Biotrue Eye Drops MDO
Hyal-Drop multi
Aqualarm U.P. intensive (0.24% sodium hyaluronate)
Biotrue Göz Damlası

ZWECKBESTIMMUNG:
Augenbefeuchtigung und Befeuchtigung und Wiederbefeuchtigung von weichen und harten Kontaktlinsen

INTENDED USE:
Eye lubricant, wetting and rewetting of both soft and rigid contact lenses during wearing.

Dr. Gerhard Mann
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Geschäftsführer
Eberhard Kühne
Manoj Kumar Panda

Amtsgericht
Charlottenburg
HRB 25425
St.-Nr. 37/004/49749
USt-IdNr. DE13 6572 946

Citibank Europe plc, Germany branch
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IBAN DE 54 5021 0900 0214 1130 07

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

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	252.124
Product (s)	Multipurpose Contact Lens Care Solutions and Lens Care Kits
GMDN Code	45870, 45088
Classification	Class IIb, Rule 15, 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: Melissa Thomas Date: April 13, 2021

Name/Title/Position: Melissa Thomas, Director, Regulatory Affairs

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

Legal Manufacturer	Bausch & Lomb Incorporated 1400 North Goodman Street Rochester, NY 14609 U.S.A.
Product (s)	Multipurpose Contact Lens Care Solutions and Lens Care Kits

Product Name GMDN 45870
Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution
Renu MultiPlus Multi-Purpose Solution
Renu Multiplus
BAUSCH + LOMB ReNu MultiPlus Multi-Purpose Solution
BAUSCH + LOMB renu fresh multi-purpose solution
BAUSCH + LOMB ReNu MPS Multi-Purpose Solution
Bausch & Lomb ReNu MPS Multi-Purpose Solution
Bausch & Lomb ReNu Multi-Purpose Solution
BAUSCH + LOMB renu multi-purpose solution
BAUSCH + LOMB renu sensitive multi-purpose solution
BAUSCH + LOMB ReNu Multi-Purpose Solution
Biotrue multi-purpose solution
Bausch + Lomb Biotrue multi-purpose solution
Biotrue multi-purpose solution flight pack
ReNu MultiPlus CARE
Renu Flight Pack
BAUSCH + LOMB renu advanced formula multi-purpose solution
Product Name GMDN 45088
Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution Kit (lens case included)
BAUSCH + LOMB ReNu MultiPlus Multi-Purpose Solution Kit (lens case included)
BAUSCH + LOMB renu fresh multi-purpose solution Kit (lens case included)
Bausch & Lomb ReNu Multi-Purpose Solution Kit (lens case included)
BAUSCH + LOMB renu multi-purpose solution Kit (lens case included)
BAUSCH + LOMB renu sensitive multi-purpose solution Kit (lens case included)
Biotrue multi-purpose solution Kit (lens case included)
Bausch + Lomb Biotrue multi-purpose solution Kit (lens case included)
Biotrue multi-purpose solution flight pack Kit (lens case included)
ReNu MultiPlus CARE Kit (lens case included)
Renu Flight Pack Kit (lens case included)
BAUSCH + LOMB renu advanced formula multi-purpose solution Kit (lens case included)
See Attachment 1 for Private Label Names

BAUSCH + LOMB

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

BAUSCH & LOMB INCORPORATED
DECLARATION OF CONFORMITY

Bausch & Lomb Incorporated declares under its sole responsibility that the product(s) listed are made in accordance with the Essential Requirements of the European Economic Community Medical Device Directive, ANNEX II [EC93/42/EEC].

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

Medical Device: Multipurpose Contact Lens Care Solutions

File Number: 252.124

Products / GMDN Code:

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution (lens case included in all sizes produced at the Milan facility: 60, 120, 240, 360 ml) / 45870
Renu MultiPlus Multi-Purpose Solution
Bausch & Lomb ReNu MPS Multi-Purpose Solution / 45870
Bausch & Lomb ReNu Multi-Purpose Solution / 45870
BAUSCH + LOMB renu multi-purpose solution / 45870
BAUSCH + LOMB renu fresh multi-purpose solution / 45870
BAUSCH + LOMB renu fresh multi-purpose solution (lens case included) / 45870
BAUSCH + LOMB renu sensitive multi-purpose solution / 45870
BAUSCH + LOMB renu sensitive multi-purpose solution (lens case included) /45870
Biotrue multi-purpose solution / 45870
Biotrue MPS/ 45870
Bausch + Lomb Biotrue multi-purpose solution / 45870
Bausch + Lomb Biotrue multi-purpose solution (lens case included) / 45870
Biotrue multi-purpose solution flight pack / 45870
BAUSCH + LOMB ReNu MultiPlus Multi-Purpose Solution / 45870
BAUSCH + LOMB ReNu Multi-Purpose Solution / 45870
BAUSCH + LOMB ReNu MPS Multi-Purpose Solution / 45870
ReNu MultiPlus CARE / 45870
Renu Multiplus (500, 360, 60ml) / 45870
Renu Flight Pack / 45870

See Attachment 1 for Private Labels

Device Class: Class IIb, Rule 15

BAUSCH + LOMB

1400 North Goodman Street
Rochester, NY 14609-3547
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www.bausch.com

Quality Management System Certificate:
Bausch & Lomb (Greenville): NSAI MD19.1854/A
Bausch & Lomb Incorporated
8507 Pelham Road
Greenville, SC 29615
USA

Bausch & Lomb (Milan): NSAI MD19.1268

Registered office address:	Manufacturing Plant address:
Via Martesana, 12	Via Pasubio, 34
20090 Vimodrone	20846 Macherio
Milano	Monza e Brianza
Italy	Italy

European Authorized Representative*:
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

*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 Surrey
KT2 6TN UK

BAUSCH+LOMB

1400 North Goodman Street
Rochester, NY 14609-3547
585.338.6000
www.bausch.com

The referenced product(s) conform to the following standards and / or other normative documents, pursuant to the provisions of the European Economic Community Medical Device Directive Regulations:

Standard	Title
EN 556:2015	Sterlization of medical devices – Requirements for medical devices to be designated 'sterile' Part 2: 2015 – Requirements for aseptically processed medical devices
EN 1041:2008	Information Supplied by the Manufacturer for Medical Devices
EN ISO 10993	Biological Evaluation of Medical Devices Part 1: 2009 – Evaluation and testing within a risk management process Part 5: 2009 – Tests for In Vitro Cytotoxicity Part 10: 2010 – Tests for Irritation and Delayed Type Hypersensitivity Part 11: 2009 – Tests for Systemic Toxicity
EN ISO 11978:2000	Contact Lenses and Contact Lens Care Products – Information Supplied by the Manufacturer
EN ISO 13212:2014	Ophthalmic Optics – Contact Lens Care Products - Guidelines for Determination of Shelf Life
EN ISO 13408	Part 1: 2015 - Aseptic Processing of Health Care Products - General Requirements Part 2: 2011 - Aseptic Processing of Health Care Products - Filtration
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice - Second Edition
EN ISO 14534:2011	Ophthalmic Optics – Contact lenses and contact lens care products – Fundamental Requirements
ISO 14729:2001	Ophthalmic Optics – Contact Lens Care Products - Microbiological Requirements and test methods for products and regimens for hygienic management of contact lenses (AMD 1 - 2010)
ISO 14730:2014	Ophthalmic Optics – Contact Lens Care Products - Antimicrobial Preservative Efficacy Testing and Guidance on Determining Discard Date
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 62366:2015	Part 1:2015 -application of usability engineering to medical devices

Signed on behalf of Bausch & Lomb Incorporated

Melissa Thomas
Director, Regulatory Affairs

Jan 24, 2020
Issuance Date

1400 North Goodman Street
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www.bausch.com

BAUSCH & LOMB INCORPORATED
DECLARATION OF CONFORMITY

Bausch & Lomb Incorporated declares under its sole responsibility that the product(s) listed are made in accordance with the Essential Requirements of the European Economic Community Medical Device Directive, ANNEX II [EC93/42/EEC].

Manufacturer:
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609, USA

Medical Device: Alphafilcon Soft Contact Lenses

Products / GMDN Code: 47843
Bausch & Lomb SofLens Toric (alphafilcon A) Visibility Tinted Contact Lenses

Device Class: Class IIa, Rule 5

Quality Management System Certificate:
Bausch & Lomb Ireland: NSAI MD19.1854/E
Unit 424/425 Contact Lens Division
Industrial Estate
Cork Road,
Waterford, Ireland

European Authorized Representative:
Bausch & Lomb Incorporated
Cork Road Industrial Estate
Waterford, X91 V383, Ireland

BAUSCH + LOMB

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Rochester, NY 14609-3547
585.338.6000
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The referenced product(s) conform to the following standards and / or other normative documents, pursuant to the provisions of the European Economic Community Medical Device Directive Regulations:

Standard	Title
EN ISO 13485:2016	Medical devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14155:2011	Clinical Investigation of Medical Devices For Human Subjects – Good Clinical Practice
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 14534:2011	Ophthalmic Optics – Contact lenses and contact lens care products – Fundamental Requirements
EN ISO 18369	Parts 1, 3-4: 2006 - Ophthalmic Optics – Contact Lenses Part 2 - Tolerances: 2012 - Ophthalmic Optics – Contact Lenses
EN ISO 11987:2012	Optics and Optical Instruments – Contact Lenses – Determination of Shelf Life
EN ISO 11981-:2009	Ophthalmic Optics – Contact Lenses and Contact Lens Care Products – Determination of physical compatibility of contact lens care products with contact lenses
EN ISO 11978:2000	Contact Lenses and Contact Lens Care Products – Information Supplied by the Manufacturer
EN ISO 10993	Biological Evaluation of Medical Devices Part 1:2009 - Evaluation and testing within a risk management process Part 5:2009 – Tests for In Vitro Cytotoxicity Part 10:2010 – Tests for Irritation and Delayed Type Hypersensitivity Part 11:2009 – Tests for Systemic Toxicity
EN ISO 17665-1:2006	Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 556-1:2001	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN 15223:2016	Graphical symbols for use in the labeling of medical devices
EN 1041:2008	Information Supplied by the Manufacturer for Medical Devices
EN ISO 11607	Packaging for terminally sterilized medical devices Part 1:2009 - Requirements for materials, sterile barrier systems and packaging systems Part 2:2006 - Validation requirements for forming, sealing and assembly processes

Signed on behalf of Bausch & Lomb Incoroporated

Nancy A. Fehrman

Nancy A. Fehrman
Senior Manager, Regulatory Affairs

Oct. 5, 2018
Issuance Date