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

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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
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KT2 6TN UK

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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 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