

**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

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:
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

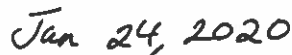
The referenced product(s) conform to the following standards and / or other normative documents, pursuant to the provisions of the European Economic Community Medical Device Directive Regulations:

| Standard | Title |
|---------------------|---|
| EN 556:2015 | Sterilization 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



Issuance Date