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].

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

Medical Device: Rigid Gas Permeable Contact Lens Cleaning Solutions

File Number: 252.283

Products / GMDN Code:

Bausch & Lomb Elite Cleaner (formula KST1) / 45866
Bausch & Lomb RGP Cleaner (formula FCP-4851) / 45866
Boston Advanced Cleaner (formula RGP3) / 45866
Boston Advanced Starter Kit (formula RGP3) / 45866
Boston Cleaner (formula KST1) / 45866
Boston ADVANCE Cleaner (formula KST-1) / 45866
Boston ADVANCE FORMULA Cleaner (formula KST-1) / 45866
Boston Linsenreiniger (formula KST-1) / 45866
Boston ADVANCE Linsenreiniger (formula KST-1) / 45866
Boston ADVANCE FORMULA (formula KST-1) / 45866
Boston Cleaner ADVANCE FORMULA (formula KST-1) / 45866
Boston Cleaner (formula RGP3) / 45866
Boston ADVANCE FORMULA Cleaner (formula RGP3) / 45866
Boston Linsenreiniger (formula RGP3) / 45866
Boston ADVANCE Linsenreiniger (formula RGP3) / 45866
Boston ADVANCE FORMULA (formula RGP3) / 45866
Boston Cleaner ADVANCE FORMULA (formula RGP3) / 45866
Boston One Step Liquid Enzymatic Cleaner (multi-dose container, formula LIQ03) / 45599
Boston One Step Liquid Enzymatic Cleaner (sample size unit-dose container, formula LIQ03) / 45599
Bausch & Lomb Boston Advance Cleaner (formula RGP3) / 45866
Bausch & Lomb Boston Advanced Cleaner (formula RGP3) / 45866

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Bausch & Lomb Boston Advance Starter Kit (formula RGP3) / 45866
Bausch & Lomb Boston Advanced Starter Kit (formula RGP3) / 45866
Bausch & Lomb Boston Original Cleaner (formula FCP-4851) / 45866
Bausch & Lomb Boston One-Step Liquid Enzymatic Cleaner (formula LIQ03) / 45599
Bausch + Lomb Concentrated Cleaner (formula FCP-4851) / 45866

See Attachment 1 for private label names

Device Class: Class IIb, Rule 15

Quality Management System Certificates:
Bausch & Lomb (Greenville): NSAI MD19.1854/A
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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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 Skin Sensitization 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 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

July 15, 2019

Issuance Date