585.338.6000

EC Declaration of Conformity

According to Directive 93/42/EEC as amended by 2007/47/EC

Bausch & Lomb Incorporated

1400 North Goodman Street Legal Manufacturer

Rochester, NY 14609

U.S.A.

European Authorized Representative(s)*

Bausch & Lomb Incorporated Cork Road Industrial Estate Waterford, X91 V383, Ireland

National Standards Authority of Ireland (NSAI)

1 Swift Square

Notified Body

Northwood, Santry Dublin 9, Ireland

Notified Body number: 0050

EC Certificate Number 252.913

Soft Corrective Contact Lens, Daily Wear and Extended Wear Product (s)

(samfilcon A)

GMDN Code 47841, 47842, and 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

Date: Syst 4, 2000 Signature:

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 Corrective Contact Lens, Daily Wear and Extended Wear (samfilcon A)

Product Name	
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	
BAUSCH + LOMB Ultra Multifocal for Astigmatism (samfilcon A) Contact Lens	
BAUSCH + LOMB Aqualox (samfilcon A) Contact Lens	
See Attachment 1 for Private Label Names	

Revision: J