

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 252.913

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

Signature:

Nancy A. Fehrman Date: Sept 9, 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

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