

## **EC Declaration of Conformity**

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

Bausch & Lomb Incorporated

Legal Manufacturer 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

National Standards Authority of Ireland (NSAI)

1 Swift Square

Notified Body

Northwood, Santry Dublin 9, Ireland

Notified Body number: 0050

EC Certificate Number 252.860

Soft Corrective Contact Lens, Daily-Disposable (nesofilcon A)

**GMDN Code** 

Product (s)

47841

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:

Christy A. Februson Date: Horil 3

Name/Title/Position:

Nancy Fehrman, Senior Manager, Regulatory Affairs

<sup>\*</sup>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-Disposable (nesofilcon A)

Product Name		
BAUSCH + LOMB Biotrue ONEday (nesofilcon A) Contact Lenses		
BAUSCH + LOMB Biotrue ONEday (nesofilcon A) For Presbyopia Contact Lenses		
BAUSCH + LOMB Biotrue ONEday (nesofilcon A) For Astigmatism Contact Lenses		
See Attachment 1 for Private Label Names		

Revision: R