DECLARATION OF CONFORMITY

(check all conformity route(s) based on EU MDD Article 11 requirements for the device class and specifics)

Annex II (4) ☐	Annex V ☐	Annex III ☐	Annex VII ☐
Annex II (3) ☒	Annex VI ☐	Annex IV ☐	

Technical Documentation Identification: DU-VC-003

Declaration of Conformity Version No.: 06

Supersedes (Date): 3/4/2019

Manufacturer: Alcon Laboratories, Inc.

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Manufacturing Site(s):

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Device (Trade Name)	GMDN Code and Term	Catalogue Number	Class
Air Optix Night & Day AQUA (Lotrafilcon A) Soft Contact Lens	47843 soft corrective contact lens, extended wear 36054 therapeutic contact lens	NA	IIb

The device(s) covered by this declaration are in conformity with the European Medical Devices Directive 93/42/EEC as well as other, relevant Union legislation that make provisions for the issuing of a declaration of conformity as listed.

Alcon Laboratories, Inc. hereby declares under its sole responsibility that the listed device(s) and Quality Systems conform(s) to:

EU MDD 93/42/EEC
as amended

This Declaration is applicable to all products listed and released after the Date of Issuance of this Declaration of Conformity, and until a revised Declaration of Conformity is issued.

Notified Body Information: Applicable ☒ Not Applicable ☐

Conformity Assessment Certificate Number(s): 597047

Notified Body: BSI

Identification number:0086

Address: Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP UK

Regulations, Directives and Standards Applied: EN ISO 13485:2016

Place of Issue: Alcon Laboratories, Inc. Fort Worth, TX USA

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