## DECLARATION OF CONFORMITY

(check all additional 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 File Number and Version: DU-VC-003 Version 04
Device Trade Name: AIR OPTIX Night & Day AQUA (lotrafilcon A) Soft Contact Lens
Supersedes (Date): 10-Dec-2020

Manufacturer: Alcon Laboratories, Inc.
Address: 6201 South Freeway,
Fort Worth, TX 76134-2099, USA

Manufacturing Site(s):

CIBA VISION Johor Sdn. Bhd.
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Johor 81560, Malaysia

PT CIBA VISION Batam
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Authorized Representative in the European Community*:
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Address: Lichterveld 3
2870 Puurs-Sint-Amands, Belgium

*Previously Alcon Laboratories (UK) Ltd.
Frimley Business Park, Frimley, Camberley Surrey, GU16 7SR, United Kingdom

| Device (Trade Name) | GMDN Code & Term | Catalogue Number | Class |
|---|---|---|---|
| AIR OPTIX Night & Day AQUA (lotrafilcon A) | 47843 Soft Corrective Contact Lens,<br>36054 Therapeutic Contact Lens,<br>Extended wear | N/A | 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, Incorporated 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): G1 020895 0393
Conformity Certificate Validity Period: 05-Feb-2021 to 26-May-2024

Notified Body: TÜV SÜD Product Service GmbH*
*Previously BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Kaynes MK5 8PP UK with identification number 0086.

Identification number: 0123

Address: Ridlerstraße 65, 80339 Munich, Germany

Regulations, Directives and Standards Applied: EN ISO 13485 as currently published

| Place of Issue: | Date of Issue: | |
|---|---|---|
| Alcon Laboratories, Incorporated, Fort Worth, TX, USA | 03-Mar-2021 | Lakota, Sherri<br>Digitally signed by Lakota, Sherri<br>DN: cn=Lakota, Sherri, ou=PDF Internal Signing, o=Alcon Vision, LLC<br>Reason: I am approving this document<br>Date: 2021.03.03 10:53:27 -06'00'<br>Adobe Acrobat DC version: 2015.006.30503<br>Name/Title/Function/Date: Sherri Lakota / VP GRA VC & DEOH |