

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-004 Version 07
 Device Trade Name: DAILIES AquaComfort Plus (nelfilcon A) Soft Contact Lens
 Supersedes (Date): 28-Oct-2020

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| Manufacturer: Alcon Laboratories, Inc. Address: 6201 South Freeway, Fort Worth, TX 76134-2099, USA Manufacturing Site(s): CIBA VISION GmbH Industriering 1, 63868 Grosswallstadt, Germany Alcon Research, LLC 11440 Johns Creek Parkway, Duluth, GA 30097, USA CIBA VISION Asian Manufacturing and Logistics Pte Ltd. 133 Tuas South Avenue 3, Singapore 637550, Singapore | Authorized Representative in the European Community*: Alcon Laboratories Belgium Address: Lichterveld 3, 2870 Puurs-Sint-Amans, Belgium *Previously Alcon Laboratories (UK) Ltd. Frimley Business Park, Frimley, Camberley Surrey, GU16 7SR, United Kingdom Alcon Laboratories Belgium BVBA** Rijksweg 14, 2870 Puurs, Belgium |
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| Device (Trade Name) | GMDN Code & Term | Catalogue Number | Class |
|---|---|------------------|-------|
| DAILIES AquaComfort Plus DAILIES AquaComfort Plus Toric DAILIES AquaComfort Plus Multifocal DAILIES AquaComfort Plus Asphere** | 47841 Soft Corrective Contact Lens, Daily-disposable | N/A | IIa |

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 Keynes 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

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| <p>Place of Issue: Alcon Laboratories, Incorporated, Fort Worth, TX, USA</p> | <p>Date of Issue: 03-Mar-2021</p> | <p>Lakota, Sherri</p> <p>Digitally signed by Lakota, Sherri DN: cn=Lakota, Sherri, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2021.03.03 10:54:29 -06'00' Adobe Acrobat DC version: 2015.006.30503</p> <p>Name/Title/Function/Date: Sherri Lakota / VP GRA VC & DEOH</p> |
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