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

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-Amands, 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

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 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 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 Name/Title/Function/Date: Sherri Lakota / VP GRA VC & DEOH