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-008 Version 02
Device Trade Name: FreshLook (phemfilcon A) Soft Contact Lenses
Supersedes (Date): 05-Oct-2020

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

Manufacturing Site(s):

PT CIBA VISION Batam
JL Beringin Lot #204, Batamindo Industrial Park
Muka Kuning, Batam Island 29433
Indonesia

Authorized Representative in the European Community*:
Alcon Laboratories Belgium
Address: Lichterveld 3
2870 Puurs-Sint-Amands, Belgium

*Previously Alcon Laboratories Belgium BVBA
Rijksweg 14, 2870 Puurs, Belgium

Device (Trade Name)	GMDN Code & Term	Catalogue Number	Class
FreshLook Handling Tint FreshLook Colors FreshLook ColorBlends FreshLook Dimensions	47842 Soft Corrective Contact Lens, Daily wear	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 10:55:21 -06'00' Adobe Acrobat DC version: 2015.006.30503 Name/Title/Function/Date: Sherri Lakota / VP GRA VC & DEOH