

**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<br>FreshLook Colors<br>FreshLook ColorBlends<br>FreshLook Dimensions | 47842 Soft Corrective Contact Lens,<br>Daily wear | N/A              | Ila   |

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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|--|-------------------------------|--|
| Place of Issue:<br>Alcon Laboratories,<br>Incorporated, Fort<br>Worth, TX, USA | Date of Issue:<br>03-Mar-2021 | <p><b>Lakota,<br/>Sherri</b></p> <p><small>Digitally signed by Lakota, Sherri<br/>                 DN: cn=Lakota, Sherri, ou=PDF Internal<br/>                 Signing, o=Alcon Vision, LLC<br/>                 Reason: I am approving this document<br/>                 Date: 2021.03.03 10:55:21 -06'00'<br/>                 Adobe Acrobat DC version: 2015.006.30503</small></p> <p>Name/Title/Function/Date: Sherri Lakota / VP GRA VC &amp; DEOH</p> |
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