

**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: DU-VC-010  
 Device Trade Name: Precision1 (Verofilcon A) Soft Contact Lens  
 Supersedes (Date): 01-Apr-2021

Manufacturer: Alcon Laboratories, Incorporated

Authorized Representative in the European Community:  
 Alcon Laboratories Belgium

Address:  
 6201 South Freeway  
 Fort Worth, Texas 76134-2099, USA

Address:  
 Lichterveld 3  
 2870 Puurs-Sint-Amands, Belgium

| Device (Trade Name)                      | GMDN Code & Term                                     | Catalogue/Model FID Number | BUDI-DI                                | Risk Class |
|--|--|----------------------------|--|------------|
| Precision1<br>Precision1 for Astigmatism | 47841 Soft Corrective Contact Lens, Daily-disposable | N/A                        | 038065GMN000218H8<br>038065GMN000219HA | 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) including revision number: G1 020895 0393 Rev.00

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: Refer to Section 4 of the Technical Documentation

Place of Issue:  
 Alcon Laboratories, Incorporated,  
 Fort Worth, TX 76134-2099, USA

Signature:

Date:

**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: 2021.05.17 14:26:50 -05'00'  
 Adobe Acrobat DC version: 2015.006.30503

Name/Title/Function: Sherri Lakota / VP GRA VC & DEOH  
 For and on behalf of Alcon Laboratories, Inc.