

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 Precision1 for Astigmatism	47841 Soft Corrective Contact Lens, Daily-disposable	N/A	038065GMN000218H8 038065GMN000219HA	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) 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:

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
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Date:

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

For and on behalf of Alcon Laboratories, Inc.