Precision1 (verofilcon A) Soft Contact Lenses, DU-VC-010

DECLARATION OF CONFORMITY (EU MDR Annex IV)			
Class, Rule	**Conformity Assessment Route**		
☐ Class III, Rule ...	☐ Annex IX	☐ Annex X + Annex XI	
☐ Class IIb, Rule ...	☐ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex IX, Chapters I and III	☐ Annex X + Annex XI
☒ Class IIa, Rule 5	☒ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex II and III + Annex XI, Section 10	☐ Annex II and III + Annex XI, Section 18
☐ Class I(s),(m),(r), Rule ...	☐ Annex II and III + Annex IX, Chapters I and III	☐ Annex II and III + Annex XI , Part A	
☐ Class I	☐ Annex II and III		
Technical Documentation Identifier: Precision1 (verofilcon A) Soft Contact Lenses (DU-VC-010) Supersedes (Date): N/A (Initial Declaration of Conformity for EU MDR)			

Manufacturer:	**Authorized Representative in the European Community**:
Name: Alcon Laboratories, Inc. Address: 6201 South Freeway Fort Worth, Texas 76134-2099 USA SRN: US-MF-000016248	Name: Alcon Laboratories Belgium Address: Lichterveld 3 2870 Puurs-Sint-Amands Belgium SRN: BE-AR-000014721

Device (Trade Name)	Catalog Number	Basic UDI-DI	EMDN Code, Term	Intended purpose
PRECISION1™ Soft Contact Lenses PRECISION1™ for ASTIGMATISM Soft Contact Lenses	N/A	038065GMN000218H8 038065GMN000219HA	Q021004 Contact Lenses	Verofilcon A soft contact lenses are intended for on-eye use in persons with healthy eyes who need vision correction as determined and fitted by an eye care professional.

The device(s) covered by this declaration are in conformity with the European Medical Devices Regulation 2017/745 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 MDR 2017/745

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: G10 020895 0396 Rev. 00
Conformity Certificate Validity Period: 28-Jul-2022 to 23-Jun-2027

Notified Body: TÜV SÜD Product Service GmbH
Identification number: 0123

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Address: Ridlerstraße 65, 80339 Munich, Germany Regulations, Directives and Standards Applied: Refer to Chapter 4 of the Technical Documentation	
Place of Issue: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Signature / Date: Brooks, Amy Digitally signed by Brooks, Amy DN: cn=Brooks, Amy, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2022.11.30 16:24:00 -06'00' Name: Amy Brooks Title/Function: Director, Global Regulatory Affairs VC & DEOH For and on behalf of Sherri Lakota, Vice President GRA VC& DEOH and Alcon Laboratories Inc.