PRECISION7 (serafilcon A) Soft Contact Lenses, DU-VC-012

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	
☐ Common Specifications applied: ☒ N/A			
☐ Other Relevant Union Legislation Declared: ☒ N/A			
☐ Class I	☐ Annex II and III		
Technical Documentation Identifier: PRECISION7 (serafilcon A) Soft Contact Lenses (DU-VC-012) Supersedes (Date): 08-Jul-2024			

Manufacturer:	**Authorized Representative in the European Union**:
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)	Model/FID Catalogue Number	Basic UDI-DI	EMDN Code, Term	Intended purpose
PRECISION7™ (serafilcon A) Soft Contact Lenses PRECISION7™ for Astigmatism (serafilcon A) Soft Contact Lenses	N/A	038065GMN000239HG 038065GMN000240GZ	Q021004, Contact Lenses	PRECISION7 (serafilcon A) soft contact lenses and PRECISION7 for Astigmatism (serafilcon A) toric soft contact lenses act as a refractive medium to focus light rays on the retina to correct vision.

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 ☐

PRECISION7 (serafilcon A) Soft Contact Lenses, DU-VC-012

Conformity Assessment Certificate Number(s) including revision number: G10 020895 0396 Rev. 08
Conformity Certificate Validity Period: 04-Jul-2024 to 23-Jun-2027

Notified Body: TÜV SÜD Product Service GmbH
Identification number: 0123
Address: Ridlerstraße 65, 80339 Munich, Germany

Regulations, Directives and Standards Applied: Refer to Chapter 4 of the Technical Documentation

Place of Issue:	Signature / Date:
Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Lakota, Sherri Digitally signed by Lakota, Sherri Date: 2024.08.30 13:27:03 -05'00' Name: Sherri Lakota Title/Function: Distinguished Fellow, Global Regulatory Affairs For and on behalf of Alcon Laboratories Inc.