

TOTAL30 (lehfilcon A) Soft Contact Lenses, DU-VC-011

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: TOTAL30 (lehfilcon A) Soft Contact Lenses (DU-VC-011) Supersedes (Date): 31-Jul-2023				
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-Amunds Belgium SRN: BE-AR-000014721		
Device (Trade Name)	Model/FID Catalogue Number	Basic UDI-DI	EMDN Code, Term	Intended purpose
TOTAL30™ spherical soft contact lenses	N/A	038065GMN000223GZ	Q021004 Contact Lenses	Lehfilcon A soft contact lenses act as a refractive medium to focus light rays on the retina to correct vision.
TOTAL30™ for ASTIGMATISM toric soft contact lenses		038065GMN000224H3		
TOTAL30™ MULTIFOCAL soft contact lenses		038065GMN000259HN		

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.

TOTAL30 (Iehfilcon A) Soft Contact Lenses, DU-VC-011

Notified Body Information: Applicable ☒ Not Applicable ☐

Conformity Assessment Certificate Number(s) including revision number: G10 020895 0396 Rev. 06
Conformity Certificate Validity Period: 13-Dec-2023 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 Section 4 of the Technical Documentation

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

Signature / Date:

Name: Amy Brooks
Title/Function: Director, GRA Vision Care
For and on behalf of Alcon Laboratories Inc.