



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

DECLARATION OF CONFORMITY (EU MDR Annex IV)				
Class, Rule		Conformity Assessment Route		
<input type="checkbox"/> Class III, Rule ...	<input type="checkbox"/> Annex IX	<input type="checkbox"/> Annex X + Annex XI		
<input type="checkbox"/> Class IIb, Rule ...	<input type="checkbox"/> Annex IX, Chapters I and III + Annex IX, Section 4	<input type="checkbox"/> Annex IX, Chapters I and III	<input type="checkbox"/> Annex X + Annex XI	
<input checked="" type="checkbox"/> Class IIa, Rule 5	<input checked="" type="checkbox"/> Annex IX, Chapters I and III + Annex IX, Section 4	<input type="checkbox"/> Annex II and III + Annex XI, Section 10	<input type="checkbox"/> Annex II and III + Annex XI, Section 18	
<input type="checkbox"/> Class I(s),(m),(r), Rule ...	<input type="checkbox"/> Annex II and III + Annex IX, Chapters I and III	<input type="checkbox"/> Annex II and III + Annex XI, Part A		
<input type="checkbox"/> Class I	<input type="checkbox"/> Annex II and III			
Technical Documentation Identifier: TOTAL30 (lehfilcon A) Soft Contact Lenses (DU-VC-011)				
Supersedes (Date): N/A (Initial Declaration of Conformity for EU MDR)				
<b>Manufacturer:</b>		<b>Authorized Representative in the European Community:</b>		
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
TOTAL30™ spherical soft contact lenses	N/A	038065GMN000223GZ	Q0210040102 Contact Lenses – Hydrogel, Reusable	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		

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  
 Address: Ridlerstraße 65, 80339 Munich, Germany

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



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

<p>Place of Issue: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA</p>	<p>Signature / Date:</p>  <p>Name: Sherri Lakota Title/Function: Vice President, Global Regulatory Affairs VC &amp; DEOH For and on behalf of Alcon Laboratories Inc.</p>
--	---