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 and Version: DU-VC-001 Version 11
Device Trade Name: AIR OPTIX (lotrafilcon B) Soft Contact Lens
Supersedes (Date): 07-Dec-2020

Manufacturer: Alcon Laboratories, Inc.
Address: 6201 South Freeway,
Fort Worth, TX 76134-2099, USA

Manufacturing Site(s):

CIBA VISION Johor Sdn. Bhd.
No. 1 Jalan DPB/5, Pelabuhan Tanjung Pelepas,
Gelang Patah, Johor Darul Takzim,
Johor 81560, Malaysia

PT CIBA VISION Batam
JL Beringin Lot #204 Batamindo Industrial Park,
Muka Kuning, Batam Island 29433, Indonesia

Authorized Representative in the European Community:
Alcon Laboratories Belgium
Address: Lichterveld 3
2870 Puurs-Sint-Amands, Belgium

Device (Trade Name)	GMDN Code & Term	Catalogue Number	Class
AIR OPTIX AIR OPTIX for Astigmatism AIR OPTIX AQUA AIR OPTIX AQUA Multifocal AIR OPTIX Plus Hydraglyde AIR OPTIX Plus HydraGlyde Multifocal AIR OPTIX Plus HydraGlyde for Astigmatism	47843 Soft Corrective Contact Lens, Extended wear	N/A	IIa

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): G1 020895 0393
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 Kaynes MK5 8PP UK with identification number 0086.

Identification number: 0123

Address: Ridlerstraße 65, 80339 Munich, Germany

Regulations, Directives and Standards Applied: EN ISO 13485 as currently published

Place of Issue:	Date of Issue:	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 Date: 2021.03.03 10:51:37 -06'00' Adobe Acrobat DC version: 2015.006.30503 Name/Title/Function/Date: Sherri Lakota / VP GRA VC & DEOH
Alcon Laboratories, Incorporated, Fort Worth, TX, USA	03-Mar-2021	