

AIR OPTIX COLORS (Iotrafilcon B with print) Soft Contact Lens, DU-VC-002

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: DU-VC-002
 Device Trade Name: AIR OPTIX COLORS (Iotrafilcon B with print) Soft Contact Lens
 Supersedes (Date): 19-May-2021

Manufacturer: Alcon Laboratories, Incorporated
 Address: 6201 South Freeway, Fort Worth, Texas 76134-2099, USA
 Authorized Representative in the European Community: Alcon Laboratories Belgium
 Address: Lichterveld 3, 2870 Puurs-Sint-Amands, Belgium

Device (Trade Name)	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
AIR OPTIX COLORS (Iotrafilcon B with print)	47842 Soft Corrective Contact Lens, Daily-wear	N/A	038065GMN000129H8	Ila

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) including revision number: G1 020895 0393 Rev. 00
 Conformity Certificate Validity Period: 05-Feb-2021 to 26-May-2024

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/Title/Function: Sherri Lakota / VP GRA VC & DEOH
 For and on behalf of Alcon Laboratories Inc.