

AIR OPTIX (Iotrafalcon B) Soft Contact Lens, DU-VC-001

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-001
 Device Trade Name: AIR OPTIX (Iotrafalcon B) Soft Contact Lens
 Supersedes (Date): 01-Apr-2021

Manufacturer: Alcon Laboratories, Incorporated

Authorized Representative in the European Community:
 Alcon Laboratories Belgium

Address:
 6201 South Freeway
 Fort Worth, Texas 76134-2099, USA

Address:
 Lichterveld 3
 2870 Puurs-Sint-Amunds, Belgium

Device (Trade Name)	GMDN Code & Term	Catalogue/Model ID Number	BUDI-DI	Risk 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	038065GMN000109H2 038065GMN000110GK 038065GMN000111GM 038065GMN000112GP 038065GMN000113GR 038065GMN000114GT 038065GMN000110GK	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*

*Previously BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP UK with identification number 0086

Identification number: 0123

Address: Ridlerstraße 65, 80339 Munich, Germany

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

AIR OPTIX (lotrafilcon B) Soft Contact Lens, DU-VC-001

<p>Place of Issue: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099, USA</p>	<p>Signature: _____ Date: _____</p> <p>Name/Title/Function: Sherri Lakota / VP GRA VC & DEOH For and on behalf of Alcon Laboratories Inc.</p>
---	---