

DAILIES TOTAL1 (delefilcon A) Soft Contact Lens, DU-VC-006

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-006
 Device Trade Name: DAILIES TOTAL1 (delefilcon A) Soft Contact Lens
 Supersedes (Date): 16-Nov-2021

Manufacturer: Alcon Laboratories, Incorporated
 Address: 6201 South Freeway
 Fort Worth, TX 76134-2099, USA
 SRN: US-MF-000016248

Authorized Representative in the European Community:
 Alcon Laboratories Belgium
 Address: Lichterveld 3
 2870 Puurs-Sint-Amands, Belgium
 SRN: BE-AR-000014721

Device (Trade Name)	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
DAILIES TOTAL1 (delefilcon A) DAILIES TOTAL1 Multifocal (delefilcon A) DAILIES TOTAL1 PRO (delefilcon A) DAILIES TOTAL1 PRO Multifocal (delefilcon A) DAILIES TOTAL1 for Astigmatism (delefilcon A)	47841 Soft Corrective Contact Lens, Daily-disposable	N/A	038065GMN000104GQ 038065GMN000106GU 038065GMN000105GS 038065GMN000107GW 038065GMN000108GY	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.
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