DECLARATION OF CONFORMITY

(check all conformity route(s) based on EU MDD Article 11 requirements for the device class and specifics)

Annex II (4) ☐ Annex V ☐ Annex III ☐
Annex II (3) ☒ Annex VI ☐ Annex IV ☐
Annex VII ☐

Technical File Number and Version: DU-VC-006 Version 8
Device Trade Name: DAILIES TOTAL1 (delefilcon A) Soft Contact Lens
Supersedes (Date) 04-Mar-2020

Manufacturer: Alcon Laboratories Inc
Address: 6201 South Freeway, Fort Worth, TX 76134 USA
Manufacturing Site(s):
CIBA VISION GmbH
Industriering 1, 63868 Grosswallstadt, Germany
Alcon Research, LLC
11460 Johns Creek Parkway Duluth, GA 30097

Authorized Representative in the European Community*
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2870 Puurs-Sint-Amands, Belgium

*Previously Alcon Laboratories (UK) Ltd.
Frimley Business Park, Frimley, Camberley Surrey. GU16 7SR, United Kingdom
Alcon Laboratories Belgium BVBA**
Rijksweg 14 2870 Puurs, Belgium

Device (Trade Name)	GMDN Code & Term	Catalogue Number	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	NA	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): CH 0208950388

Notified Body: TÜV SÜD Product Service GmbH
**Previously BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP UK with identification number 0086.

Identification number: 0123

Address: Ridlerstraße 65 D-80339 München, Germany

Technical File Number and Version:

DU-VC-006 VERSION 8

Regulations, Directives and Standards Applied: EN ISO 13485 as currently published		
Place of Issue Alcon Laboratories Incorporated Fort Worth, TX USA	Date of Issue 05-19-20	Lakota Sherri Name/Title/Function/Date: Sherri Lakota/VP GRA VC & OEOH