

DECLARATION OF CONFORMITY		
(check all conformity route(s) based on EU MDD Article 17 requirements for the device class and specifics)		
Annex II (4) <input type="checkbox"/>	Annex V <input type="checkbox"/>	Annex III <input type="checkbox"/>
Annex II (3) <input checked="" type="checkbox"/>	Annex VI <input type="checkbox"/>	Annex IV <input type="checkbox"/>
		Annex VII <input type="checkbox"/>

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, 83068 Grosswallstadt, Germany
 Alcon Research, LLC
 11440 Johns Creek Parkway, Duluth, GA 30097

Authorized Representative in the European Community*
 Alcon Laboratories Belgium
 Address: Lichterveld 3
 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	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): G1 020896 0388

Notified Body: TÜV SÜD Product Service GmbH
 **Previously BSI, Kitepark Court, Davy Avenue, Kitepark Hill, Milton Keynes MK5 8PP UK with identification number D086.
 identification number: 0123

Address: Rüdigerstraße 65 D-80335 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: <i>05-19-20</i>	Lakota Sherri <small>Digitally signed by Lakota Sherri DN: cn=Lakota Sherri, o=Alcon, ou=Alcon, email=Lakota.Sherri@alcon.com, c=US</small> Name/Title/Function/Date: Sherri Lakota/VP GRA VC & DEOH

Technical File Number and Version:

DU-VC-006 VERSION 8