

DECLARATION OF CONFORMITY		
(check all conformity route(s) based on EU MDD Article 17 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, 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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP UK with identification number D086.

Identification number: 0123

Address: Rüdlerstraße 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:

05-19-20

Lakota Sherri

Digitally signed by Lakota Sherri
DN: cn=Lakota Sherri, o=Alcon, ou=Alcon, email=Lakota.Sherri@alcon.com, c=US

Name/Title/Function/Date: Sherri Lakota/VP GRA VC & DEOH

Technical File Number and Version:

DU-VC-006 VERSION 8