

TOTAL30 (lehfilcon A) Soft Contact Lenses, DU-VC-011

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-011
 Device Trade Name: TOTAL30 (lehfilcon A) Soft Contact Lenses
 Supersedes (Date): 17-May-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-Amands, Belgium

SRN:
 US-MF-000016248

SRN:
 BE-AR-000014721

Device (Trade Name)	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
TOTAL30 (lehfilcon A) Soft Contact Lenses	47842 Soft Corrective Contact Lens, Daily-wear	N/A	038065GMN000223GZ	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*

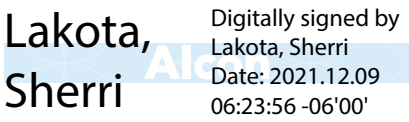
This Declaration is applicable to all products listed and released after the Date of Issuance of this Declaration of Conformity, and until a revised Declaration of Conformity is issued.

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:  Digitally signed by Lakota, Sherri Date: 2021.12.09 06:23:56 -06'00'
Name/Title/Function: Sherri Lakota / VP GRA VC & DEOH For and on behalf of Alcon Laboratories, Inc.	