

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:

Lakota, Sherri
 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.