

AOSEPT PLUS with Hydraglyde FID 120947A, FW-VC-004

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: FW-VC-004

Device Trade Name: AOSEPT PLUS with Hydraglyde FID 120947A (with AOCup Lens Case)

Supersedes (Date): 20-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

Device (Trade Name)	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
AOSEPT PLUS with Hydraglyde	48074 Multi-purpose soft/rigid contact lens solution	120947A	038065GMN000017GU	IIb
AOCup Lens Case	n/a	9009469 9012659 9013866	n/a (covered under above BUDI-DI of the solution)	n/a

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:

Sherri Lakota 28 Oct 2021

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

For and on behalf of Alcon Laboratories Inc.