

AOSEPT PLUS FID 119056, FW-VC-003

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-003

Device Trade Name: AOSEPT PLUS FID 119056 (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) ^a	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
AOSEPT PLUS	48074 Multi-purpose soft/rigid contact lens solution	119056	038065GMN000016GS	IIb
AOCup Lens Case	n/a	9009469 9012659 9013866	n/a (covered under above BUDI-DI of the solution)	n/a

^aSee page 2 for alternate names

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:

 28 Oct 2021

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

For and on behalf of Alcon Laboratories Inc.

ALTERNATE NAMES

AOSEPT PLUS FID 119056 is also marketed with the following alternate names:

AOSEPT Hi Tech
 ASDA One Step Peroxide
 Binop PREMIUM One Step Peroxid
 Binop PREMIUM Peroxid
 Boots Deep Cleaning System
 Boots Preservative Free Deep Cleaning System
 Deep Cleaning System
 Dublan Peróxido Plus
 Dynaeasy 4
 Eyexpert Actisept
 EYEplusCON Desinfektionslösung PLUS
 Eyeeye Monosept
 Focus Platinum
 GN Sept PLUS
 IS Night Perossido Plus
 iWear Actisept
 iWear Aqua+
 iWear Peroxyde Supreme+
 Lens View PX Desinfektionslösung PLUS
 LENSY CARE
 LENTSOFT
 Lumens Plus
 Medi SEPT
 Multisept PLUS
 NovaSept
 Novasept Comfort
 Oculsoft Premium Clear
 Oculsoft Premium Clear Care
 Oculsoft Premium Crystal Care
 Oculsoft Sensitive Peroxid
 OPTIview Disc+
 OTTICA AMICA PEROSSIDO PLUS
 P250 PLUS CLEAN
 Perossido Plus Ottica Amica
 PremiumSept Ultra
 Primasept Ultra
 ProEye Disc+
 Purrelens Softcare Monosept
 Rayner PLUS 1 DISC CARE SYSTEM
 Royal Monosept Plus
 SEHENSWERT PLATIN Premium
 SOFTCARE MONOSEPT
 TemPLUS
 Tesco Peroxide One Step
 VISILENSCare INTENSIVE