

**SYSTANE COMPLETE Lubricant Eye Drops FID 122505, FW-PH-018**

**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-PH-018

Device Trade Name: SYSTANE COMPLETE Lubricant Eye Drops FID 122505

Supersedes (Date): 23-Aug-2021

Manufacturer: Alcon Laboratories, Incorporated

Authorized Representative in the European Community:  
Alcon Laboratories Belgium

Address:

6201 South Freeway  
Fort Worth, TX 76134-2099 USA

Address: Lichterveld 3  
2870 Puurs-Sint-Amands, Belgium

Device (Trade Name) <sup>a</sup>	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
SYSTANE Complete Lubricant Eye Drops 3 mL fill / 11 mL bottle 10 mL fill / 11 mL bottle	44237 Eye Lubricant	FID 122505	038065GMN000230GW	Ila

<sup>a</sup>See 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

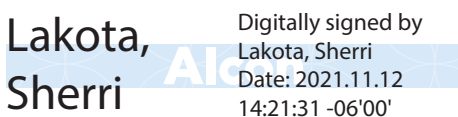
Conformity Certificate Validity Period: 05-Feb-2021 to 26-May-2024

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:   Digitally signed by Lakota, Sherri Date: 2021.11.12 14:21:31 -06'00'  Name/Title/Function: Sherri Lakota/Vice President/GRA Vision Care & Dry Eye Ocular Health For and on behalf of Alcon Laboratories Inc.
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**SYSTANE COMPLETE Lubricant Eye Drops FID 122505, FW-PH-018**

**ALTERNATE NAMES**

SYSTANE COMPLETE Lubricant Eye Drops FID 122505 is also marketed with the following alternate names:

SYSTANE COMPLETE Preservative-Free Lubricant Eye Drops

SYSTANE COMPLETE Multi-Dose Preservative Free (MDPF) Lubricant Eye Drops