

**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): 12-Nov-2021

Manufacturer: Alcon Laboratories, Inc.  
 Address: 6201 South Freeway  
 Fort Worth, TX 76134-2099, USA

Authorized Representative in the European Community:  
 Alcon Laboratories Belgium  
 Address: Lichterveld 3  
 2870 Puurs-Sint-Amands, Belgium

SRN: US-MF-000016248                      SRN: BE-AR-000014721

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:          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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**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