SYSTANE ULTRA Lubricant Eye Drops FID 114473, FW-PH-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: FW-PH-011

Device Trade Name: SYSTANE ULTRA Lubricant Eye Drops FID 114473

Supersedes (Date): 17-Feb-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

Device (Trade Name)	GMDN Code & Term	Catalogue Number	BUDI-DI	Class
SYSTANE ULTRA UD Lubricant Eye Drops 0.5 mL fill / 0.8 mL vial 0.5 mL fill / 1.6 mL vial 0.7 mL fill / 1.2 mL vial 0.7 mL fill / 1.6 mL vial (Unit Dose) SYSTANE ULTRA Lubricant Eye Drops 3 mL fill / 11 mL bottle 10 mL fill / 11 mL bottle (Multi-Dose, Preservative Free)	48082 Contact Lens Wetting Solution	FID 114473	038065GMN000086HF	IIb

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): 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: See Section 4.2 of the CE Technical File

Place of Issue:
Alcon Laboratories, Incorporated
Fort Worth, TX USA

Lakota, Sherri

Digitally signed by Lakota, Sherri
DN: cn=Lakota, Sherri, ou=PDF Internal Signing, o=Alcon Vision, LLC
Reason: I am approving this document
Date: 2021.05.18 15:45:43 -05'00'
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Name/Title/Function/Date: Sherri Lakota/Vice President/GRA Vision Care & Dry Eye Ocular Health