SYSTANE Gel Drops Lubricant Eye Gel FID 115958D, FW-PH-008

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-008 Version 09

Device Trade Name: SYSTANE Gel Drops Lubricant Eye Gel FID 115958D

Supersedes (Date): 01-Sep-2020

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

Manufacturing Site(s):
Alcon Singapore Manufacturing Pte. Ltd.
19 Tuas South Avenue 14, Singapore 637313

Contract Manufacturer:
Alcon Cusí S.A.
Camil Fabra, 58, Apartado 2
08320 El Masnou (Barcelona), Spain

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

*Previously: Alcon Laboratories (UK) Ltd.
Frimley Business Park Frimley, Camberley Surrey,
GU16 7SR, United Kingdom

Device (Trade Name)	GMDN Code & Term	Catalogue Number	BUDI-DI	Class
SYSTANE Gel Drops Lubricant Eye Gel, 3 mL, 5 mL & 10 mL	44237 Eye Lubricant	FID 115958D	038065GMN000083H9	IIa

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
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: EN ISO 13485 as currently published

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: 2021.02.16 11:19:24 -06'00'
Adobe Acrobat DC version: 2015.006.30503

Name/Title/Function/Date: Sherri Lakota/Vice President/GRA Vision Care & Dry Eye Ocular Health