DECLARATION OF CONFORMITY

(check all conformity route(s) based on EU MDD Article 11 requirements for the device class and specifics)

Annex II (4) ☐ Annex V ☐ Annex III ☐
Annex II (3) ☒ Annex VI ☐ Annex IV ☐
Annex VII ☐

Technical File Number and Version: FW-PH-012 Version 04
Device Trade Name: SYSTANE HYDRATION Lubricant Eye Drops FID 119515A
Supersedes (Date): 05-Aug-2019

Manufacturer: Alcon Laboratories, Inc.
Address: 6201 South Freeway, Fort Worth, TX 76134 USA
Manufacturing Site(s):
Contract Manufacturer:
Alcon Cusi S.A.
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08320 El Masnou (Barcelona), Spain

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

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Frimley Business Park Frimley, Camberley Surrey, GU16 7SR, United Kingdom

Device (Trade Name)	GMDN Code & Term	Catalogue Number	Class
SYSTANE HYDRATION Lubricant Eye Drops	44237 eye lubricant 48082 Contact lens wetting solution	FID 119515A	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 0345

Notified Body: TÜV SÜD Product Service GmbH

Identification number: 0123

Address: Ridlerstraße 65 D-80339 München, Germany

Regulations, Directives and Standards Applied: EN ISO 13485 as currently published

Place of Issue:	Date of Issue:	
Alcon Laboratories, Incorporated, Fort Worth, TX USA	01-13-20	Lakota Sherri Digitally signed by Lakota Sherri DN: dc=com, dc=novartis, ou=people, ou=AL, serialNumber=1428040, cn=Lakota Sherri Date: 2020.01.13 08:05:19 -06'00' Name/Title/Function/Date: Sherri Lakota/VP GRA VC & DEOH