

SYSTANE HYDRATION Lubricant Eye Drops FID 121843, FW-PH-013

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-013

Device Trade Name: SYSTANE HYDRATION Lubricant Eye Drops FID 121843

Supersedes (Date): 18-May-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) ^a	GMDN Code & Term	Catalogue Number	BUDI-DI	Class
SYSTANE HYDRATION UD Lubricant Eye Drops 0.7 mL fill / 1.16 mL vial (Unit Dose) SYSTANE HYDRATION Lubricant Eye Drops 3 mL fill / 11 mL bottle 10 mL fill / 11mL bottle (Multi-Dose, Preservative Free)	48082 Contact Lens Wetting Solution	FID 121843	038065GMN000088HK	IIb

^aSee 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): 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 USA	Signature/Date: <div style="text-align: center;"> Digitally signed by Lakota, Sherri Date: 2022.02.25 16:36:44 -06'00' </div> 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 HYDRATION Lubricant Eye Drops FID 121843 is also marketed with the following alternate names:

Unit Dose (UD):	SYSTANE HYDRATION SYSTANE HYDRATION Lubricant Eye Drops SYSTANE HYDRATION Moisture Contacts Eye Drops SYSTANE HYDRATION UD Lubricant Eye Drops SYSTANE HYDRATATION SYSTANE HYDRATACIÓN UD SYSTANE IDRA SYSTANE Ultra Plus Hidratação UD SYSTANE Ultra Plus Hidratación UD
Multi-Dose Preservative Free (MDPF):	SYSTANE HYDRATION Lubricant Eye Drops SYSTANE HYDRATION MDPF Lubricant Eye Drops SYSTANE Ultra Plus Lubricant Eye Drops SYSTANE Ultra Plus SP SYSTANE HYDRATION PRESERVATIVE-FREE SYSTANE HYDRATION PRESERVATIVE-FREE Lubricant Eye Drops SYSTANE HYDRATION PF