

**SYSTANE HYDRATION Lubricant Eye Drops FID 119515A, FW-PH-012**

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) <input type="checkbox"/>	Annex V <input type="checkbox"/>	Annex III <input type="checkbox"/>	Annex VII <input type="checkbox"/>	
Annex II (3) <input checked="" type="checkbox"/>	Annex VI <input type="checkbox"/>	Annex IV <input type="checkbox"/>		
Technical File Number: FW-PH-012 Device Trade Name: SYSTANE HYDRATION Lubricant Eye Drops FID 119515A Supersedes (Date): 16-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 HYDRATION Lubricant Eye Drops 1.5 mL fill / 4 mL oval bottle 3 mL fill / 8 mL bottle 5 mL fill / 8 mL bottle 10 mL fill / 10 mL bottle	48082 Contact Lens Wetting Solution	FID 119515A	038065GMN000093HC	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:  <div style="text-align: center;"><i>EU MDD 93/42/EEC as amended</i></div> 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 <input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/>  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	Name/Title/Function/Date: Sherri Lakota/Vice President/GRA Vision Care & Dry Eye Ocular Health			