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Approved Date:

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## OPTI-FREE EXPRESS MPDS FID 90746, FW-VC-005

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 II (4) □ Annex V □		Annex VII (	Annex VII □	
Annex II (3) ⊠	Annex VI □	Annex IV □			
Technical File Number: FW-VC-005 Device Trade Name: OPTI-FREE EXPRESS MPDS FID 90746 (with Alcon Contact Lens Case (Flat)) Supersedes (Date): 20-May-2021					
Manufacturer: Alcon Laboratories, Incorporated		Authorized Representative in the European Community; Alcon Laboratories Belgium			
Address: 6201 South Freeway Fort Worth, Texas 76134-2099, USA		Address: Lichterveld 3 2870 Puurs-Sint-Amands, Belgium			
Device (Trade Name)ª	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class	
OPTI-FREE EXPRESS MPDS	45870 Multi-purpose soft contact lens solution	90746	038065GMN000098HN	IIb	
Alcon Contact Lens Case (Flat)	n/a	213180 213240 201100 9010169	n/a (covered under above BUDI-DI of the solution)	n/a	
<sup>a</sup> See 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) including revision number: 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					

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Alcon

## OPTI-FREE EXPRESS MPDS FID 90746, FW-VC-005

Place of Issue:

Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA

Signature:

Date:

Name/Title/Function: Sherri Lakota / VP GRA VC & DEOH

For and on behalf of Alcon Laboratories Inc.

## **ALTERNATE NAMES**

OPTI-FREE EXPRESS MPDS FID 90746 is also marketed with the following alternate names:

OPTI-FREE® EXPRESS® Multi-Purpose Disinfecting Solution

eyewish® Lens Care Solution No Rub

iWear® Lens Care Solution No Rub

**EYECARE Disinfection MPDS** 

Polyflex Express MPDS

LISSAC MULTI-FONCTIONS

Dia Plus

I-WEAR® All-In-One Supreme Plus Multi-Purpose Disinfecting Solution

Eyexpert Extrasoft

iWear Extracomfort