

## DECLARATION OF CONFORMITY

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

Annex II (4)  Annex V  Annex II  Annex VI: L  
 Annex II (3)  Annex VI: L  Annex: VI

Technical Documentation identification: FW-VC-007

Declaration of Conformity Version No.: 02

Supersedes (Date): 11/26/2018

Manufacturer: Alcon Laboratories, Inc.

Authorized Representative in the European  
Community: Alcon Laboratories (UK) LtdAddress: 6201 South Freeway Fort Worth, TX  
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Manufacturing Site(s):

*Alcon Research, Ltd.**Fort Worth North Mfg. Facility*

Device (Trade Name)	GMDN Code and Form	Catalogue Number	Class
OPTI-FREE PureMoist MPDS	45870 Multi purpose soft contact lens solution	114675A	Ib

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, Inc. 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 320885 0345 Rev. 01

Notified Body: TÜV SÜD Product Service GmbH

Identification number: 0123

Address: Ridlerstraße 65 D-80339 München, Germany

Regulators, Directives, and Standards Applied: EN ISO 13485:2012

Place of Issue: Alcon Laboratories, Inc. Fort Worth, TX USA  
 Date of Issue: 12-04-18  
 Signature: Lakota Sherri  
 Name: Sherri Lakota  
 Title/Function: Sr. Director GHA VC  
 Date: \_\_\_\_\_

