DECLARATION OF CONFORMITY

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

Annex II (4) ☐ Annex V ☐ Annex III ☐ Annex VII ☐

Annex II (3) ☒ Annex VI ☐ Annex IV ☐

Technical Documentation identification: FW-VC-007

Declaration of Conformity Version No.: 02

Supersedes (Date): 11/26/2018

Manufacturer: Alcon Laboratories, Inc.

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Manufacturing Site(s):

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Fort Worth North Mfg. Facility

Authorized Representative in the European Community: Alcon Laboratories (UK) Ltd

Address: *Frimley Business Park Frimley, Camberley Surrey, GU16 7SR, United Kingdom*

Device (Trade Name)	GMDN Code and Term	Catalogue Number	Class
OPTI-FREE PureMoist MPDS	45870 Multi purpose soft contact lens solution	114675A	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, 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 020895 0345 Rev. 01

Notified Body: TÜV SÜD Product Service GmbH

Identification number: 0123

Address: Ridlerstraße 65 D-80339 München, Germany

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

Place of Issue: Alcon Laboratories, Inc. Fort Worth, TX USA

Date of Issue: 12-04-18

Signature: Lakota Sherri [redacted] Date: _____

Name: Sherri Lakota

Title/Function: Sr. Director GRA VC