DECLARATION OF CONFORMITY

(check all 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 Documentation Identification: FW-VC-005

Declaration of Conformity Version No.: 0

Supersedes (Date): 6/28/2016

Manufacturer: Alcon Laboratories, Inc.

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Manufacturing Site(s):

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

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Device (Trade Name)	GMDN Code and Term	Catalogue Number	Class
OPT-FREE EXPRESS MPDS	45870 Multi-purpose soft contact lens solution	FID 90746	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

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: 03-05-19

Signature: Lakota Sherri [redacted] Date: _____

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