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 II ☐ Annex VI ☐

Annex I (3) ☒ Annex VII ☐ Annex IV ☐

Technical Documentation Identification: FW-VC-004

Declaration of Conformity Version No.: 04

Supersedes (Date): 11/26/2018

Manufacturer: Alcon Laboratories, Inc.

Address: 6201 South Freeway Fort Worth, TX 76134 USA

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
AOSEPT® PLUS with HydraGlyde®	48074 Multi-purpose soft/rigid contact lens solution	FID 120947A	I b

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 Date:

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Title/Function: Sr. Director GRA VC