

AcrySof Single-Piece Intraocular Lenses, FW-SG-009

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 V ☐

Annex III ☐

Annex VII ☐

Annex II (3) ☒

Annex VI ☐

Annex IV ☐

Technical File Number: FW-SG-009

Device Trade Name: AcrySof Single-Piece Intraocular Lens

Supersedes (Date): 12-May-2021

Manufacturer: Alcon Laboratories, Incorporated

Address: 6201 South Freeway, Fort Worth, TX

76134-2099, USA

Authorized Representative in the European Community:

Alcon Laboratories Belgium

Address: Lichterveld 3

2870 Puurs-Sint-Amands

Belgium

Device (Trade Name)	GMDN Code & Term	Catalogue/Model Number	BUDI-DI	Risk Class
AcrySof IQ Aspheric Natural Intraocular Lens	35658 Posterior Chamber Intraocular Lens pseudophakic	SN60WF	038065GMN000053GY	IIb
AcrySof Natural Single-Piece Intraocular Lens		SN60AT	038065GMN000054H2	
AcrySof Aspheric UV Absorbing Intraocular Lens		SA60WF	038065GMN000056H6	
AcrySof Single-Piece Intraocular Lens		SA60AT	038065GMN000055H4	
AcrySof IQ Toric Astigmatism Intraocular Lens		SN6AT2 SN6AT3 SN6AT4 SN6AT5 SN6AT6 SN6AT7 SN6AT8 SN6AT9	038065GMN000057H8	
AcrySof IQ Aspherical UV-Absorbing Toric Intraocular Lens		SA6AT2 SA6AT3 SA6AT4 SA6AT5 SA6AT6 SA6AT7 SA6AT8 SA6AT9	038065GMN000058HA	

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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): G1 020895 0393, Revision 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

Place of Issue:

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



Date: 02-Dec-2021

Stephanie Baker, Vice President, Global Regulatory Affairs, Surgical