

# Clareon Intraocular Lens with the AutonoMe Automated Pre-loaded Delivery System, FW-SG-041

## 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 II (3) ☒

Annex VI ☐

Annex IV ☐

Annex VII ☐

Technical File Number: FW-SG-041

Device Trade Name: : Clareon Intraocular Lens with the AutonoMe Automated Pre-loaded Delivery System

Supersedes (Date): 02-Mar-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-Amans, Belgium

| Device (Trade Name)                                                                             | GMDN Code & Term                                          | Catalogue Number/ Model Number                                                                             | BUDI-DI           | Risk Class |
|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-------------------|------------|
| Clareon Aspheric Hydrophobic Acrylic IOL with the AutonoMe Automated Pre-loaded Delivery System | 35658<br>Posterior-chamber intraocular lens, pseudophakic | CNA0T0                                                                                                     | 038065GMN000139HB | I Ib       |
| Clareon Aspheric UV Absorbing IOL with the AutonoMe Pre-loaded Delivery System                  | 35658<br>Posterior-chamber intraocular lens, pseudophakic | CCA0T0                                                                                                     | 038065GMN000140GU | I Ib       |
| Clareon Toric Aspheric UV-Absorbing Hydrophobic Acrylic IOL with the AutonoMe Delivery System   | 35658<br>Posterior-chamber intraocular lens, pseudophakic | CCA0T2, CCA0T3<br>CCA0T4, CCA0T5<br>CCA0T6, CCA0T7<br>CCA0T8, CCA0T9<br><br>(collectively known as CCA0TT) | 038065GMN000141GW | I Ib       |
| Clareon Toric Aspheric Hydrophobic Acrylic IOL with the AutonoMe Delivery System                | 35658<br>Posterior-chamber intraocular lens, pseudophakic | CNA0T2, CNA0T3<br>CNA0T4, CNA0T5<br>CNA0T6, CNA0T7<br>CNA0T8, CNA0T9<br><br>(collectively known as CNA0TT) | 038065GMN000142GY | I Ib       |

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------|-------------------|-----|
| Clareon PanOptix Trifocal Hydrophobic IOL with the AutonoMe Automated Pre-loaded Delivery System<br><br><i>Previously referenced as: Clareon PanOptix Trifocal Intraocular Lens with the AutonoMe Pre-loaded Delivery System</i>               | 35658<br>Posterior-chamber intraocular lens, pseudophakic | CNATT0                                                                       | 038065GMN000143H2 | IIb |
| Clareon PanOptix Trifocal UV Absorbing IOL with the AutonoMe Automated Pre-loaded Delivery System<br><br><i>Previously referenced as: Clareon PanOptix UV Absorbing Trifocal Intraocular Lens with the AutonoMe Pre-Loaded Delivery System</i> | 35658<br>Posterior-chamber intraocular lens, pseudophakic | CCATT0                                                                       | 038065GMN000144H4 | IIb |
| Clareon PanOptix Toric Trifocal Hydrophobic IOL with the AutonoMe Automated Pre-loaded Delivery System                                                                                                                                         | 35658<br>Posterior-chamber intraocular lens, pseudophakic | CNATT2, CNATT3, CNATT4, CNATT5, CNATT6<br><br>(collectively known as CNATTT) | 038065GMN000221GV | IIb |
| Clareon PanOptix Toric Trifocal UV Absorbing IOL with the AutonoMe Automated Pre-loaded Delivery System                                                                                                                                        | 35658<br>Posterior-chamber intraocular lens, pseudophakic | CCATT2, CCATT3, CCATT4, CCATT5, CCATT6<br><br>(collectively known as CCATTT) | 038065GMN000222GX | 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, 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

## Clareon Intraocular Lens with the AutonoMe Automated Pre-loaded Delivery System, FW-SG-041

Place of Issue:  
Alcon Laboratories, Incorporated,  
Fort Worth, TX 76134-2099 USA

Lemke, Sylvia

Digitally signed by Lemke, Sylvia  
DN: cn=Lemke, Sylvia, ou=PDF Internal Signing,  
o=Alcon Vision, LLC  
Reason: I am approving this document  
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Sylvia Lemke, Senior Director, Global Regulatory Affairs