AIR OPTIX (lotrafilcon B) Soft Contact Lens, DU-VC-001

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: DU-VC-001
Device Trade Name: AIR OPTIX (lotrafilcon B) Soft Contact Lens
Supersedes (Date): 07-Jun-2022

Manufacturer:
Alcon Laboratories, Incorporated

Address:
6201 South Freeway
Fort Worth, Texas 76134-2099, USA

SRN:
US-MF-000016248

Authorized Representative in the European Community:
Alcon Laboratories Belgium

Address:
Lichterveld 3
2870 Puurs-Sint-Amands, Belgium

SRN:
BE-AR-000014721

Device (Trade Name)	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
AIR OPTIX AIR OPTIX for Astigmatism	47843 Soft Corrective Contact Lens, Extended-wear	N/A	038065GMN000109H2 038065GMN000112GP	IIa
AIR OPTIX AQUA AIR OPTIX AQUA Multifocal			038065GMN000110GK 038065GMN000114GT	
AIR OPTIX Plus Hydraglyde AIR OPTIX Plus HydraGlyde Multifocal AIR OPTIX Plus HydraGlyde for Astigmatism			038065GMN000111GM 038065GMN000115GV 038065GMN000113GR	

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) including revision number: G1 020895 0393 Rev. 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:	Signature / Date:
Alcon Laboratories, Incorporated, Fort Worth, Texas 76134-2099, USA	Brooks, Amy Digitally signed by Brooks, Amy DN: cn=Brooks, Amy, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2022.12.09 21:49:50 -06'00' Name/Title/Function: Amy Brooks / Director / GRA VC For and on behalf of Sherri Lakota / VP GRA VC & DEOH and Alcon Laboratories Inc.

AIR OPTIX Night & Day AQUA (lotrafilcon A) Soft Contact Lens, DU-VC-003

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: DU-VC-003
Device Trade Name: AIR OPTIX Night & Day AQUA (lotrafilcon A) Soft Contact Lens
Supersedes (Date): 02-Mar-2022

Manufacturer:
Alcon Laboratories, Incorporated

Address:
6201 South Freeway
Fort Worth, TX 76134-2099, USA

SRN:
US-MF-000016248

Authorized Representative in the European Community:
Alcon Laboratories Belgium

Address:
Lichterveld 3
2870 Puurs-Sint-Amands, Belgium

SRN:
BE-AR-000014721

Device (Trade Name)	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
AIR OPTIX Night & Day AQUA (lotrafilcon A)	47843 Soft Corrective Contact Lens, 36054 Therapeutic Contact Lens, Extended wear	N/A	038065GMN000116GX 038065GMN000117GZ	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) including revision number: G1 020895 0393 Rev. 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

Signature / Date:

Lakota, Sherri

Digitally signed by Lakota, Sherri
Date: 2022.03.22 17:35:51 -05'00'

Name/Title/Function: Sherri Lakota / VP GRA VC & DEOH
For and on behalf of Alcon Laboratories Inc.

DAILIES TOTAL1 (delefilcon A) Soft Contact Lens, DU-VC-006

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: DU-VC-006

Device Trade Name: DAILIES TOTAL1 (delefilcon A) Soft Contact Lens

Supersedes (Date): 16-Nov-2021

Manufacturer:
Alcon Laboratories, Incorporated

Address:
6201 South Freeway
Fort Worth, TX 76134-2099, USA

SRN:
US-MF-000016248

Authorized Representative in the European Community:
Alcon Laboratories Belgium

Address:
Lichterveld 3
2870 Puurs-Sint-Amands, Belgium

SRN:
BE-AR-000014721

Device (Trade Name)	GMDN Code & Term	Catalogue/Model FID Number	BUDI-DI	Risk Class
DAILIES TOTAL1 (delefilcon A) DAILIES TOTAL1 Multifocal (delefilcon A) DAILIES TOTAL1 PRO (delefilcon A) DAILIES TOTAL1 PRO Multifocal (delefilcon A) DAILIES TOTAL1 for Astigmatism (delefilcon A)	47841 Soft Corrective Contact Lens, Daily-disposable	N/A	038065GMN000104GQ 038065GMN000106GU 038065GMN000105GS 038065GMN000107GW 038065GMN000108GY	IIa

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) including revision number: G1 020895 0393 Rev. 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

Signature / Date:

Lakota, Sherri

Digitally signed by Lakota, Sherri
Date: 2022.08.23 11:06:19 -05'00'

Name/Title/Function: Sherri Lakota / VP GRA VC & DEOH

For and on behalf of Alcon Laboratories Inc.

Precision1 (verofilcon A) Soft Contact Lenses, DU-VC-010

DECLARATION OF CONFORMITY (EU MDR Annex IV)			
Class, Rule	**Conformity Assessment Route**		
☐ Class III, Rule ...	☐ Annex IX	☐ Annex X + Annex XI	
☐ Class IIb, Rule ...	☐ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex IX, Chapters I and III	☐ Annex X + Annex XI
☒ Class IIa, Rule 5	☒ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex II and III + Annex XI, Section 10	☐ Annex II and III + Annex XI, Section 18
☐ Class I(s),(m),(r), Rule ...	☐ Annex II and III + Annex IX, Chapters I and III	☐ Annex II and III + Annex XI , Part A	
☐ Class I	☐ Annex II and III		
☐ Common Specifications applied: ☒ N/A			
☐ Other Relevant Union Legislation Declared: ☒ N/A			
Technical Documentation Identifier: Precision1 (verofilcon A) Soft Contact Lenses (DU-VC-010) Supersedes (Date): 31-Jul-2023			

Manufacturer:	**Authorized Representative in the European Union**:
Name: Alcon Laboratories, Inc. Address: 6201 South Freeway Fort Worth, Texas 76134-2099 USA SRN: US-MF-000016248	Name: Alcon Laboratories Belgium Address: Lichterveld 3 2870 Puurs-Sint-Amands Belgium SRN: BE-AR-000014721

Device (Trade Name)	Model/FID Catalogue Number	Basic UDI-DI	EMDN Code, Term	Intended purpose
PRECISION1™ Soft Contact Lenses PRECISION1™ for ASTIGMATISM Soft Contact Lenses	N/A	038065GMN000218H8 038065GMN000219HA	Q021004 Contact Lenses	Verofilcon A soft contact lenses are intended for on-eye use in persons with healthy eyes who need vision correction as determined and fitted by an eye care professional.

The device(s) covered by this declaration are in conformity with the European Medical Devices Regulation 2017/745 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 MDR 2017/745

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.

Precision1 (verofilcon A) Soft Contact Lenses, DU-VC-010

Notified Body Information: Applicable ☒ Not Applicable ☐

Conformity Assessment Certificate Number(s) including revision number: G10 020895 0396 Rev. 06
Conformity Certificate Validity Period: 13-Dec-2023 to 23-Jun-2027

Notified Body: TÜV SÜD Product Service GmbH
Identification number: 0123
Address: Ridlerstraße 65, 80339 Munich, Germany

Regulations, Directives and Standards Applied: Refer to Chapter 4 of the Technical Documentation

Place of Issue: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Signature / Date: Brooks, Amy Digitally signed by Brooks, Amy DN: cn=Brooks, Amy, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2023.12.21 10:23:19 -06'00' Name: Amy Brooks Title/Function: Director, GRA Vision Care For and on behalf of Alcon Laboratories Inc.

TOTAL30 (lehfilcon A) Soft Contact Lenses, DU-VC-011

DECLARATION OF CONFORMITY (EU MDR Annex IV)			
Class, rule	**Conformity Assessment Route**		
☐ Class III, rule ...	☐ Annex IX	☐ Annex X + Annex XI	
☐ Class IIb, rule ...	☐ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex IX, Chapters I and III	☐ Annex X + Annex XI
☒ Class IIa, rule 5	☒ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex II and III + Annex XI, Section 10	☐ Annex II and III + Annex XI, Section 18
☐ Class I(s),(m),(r), rule ...	☐ Annex II and III + Annex IX, Chapters I and III	☐ Annex II and III + Annex XI , Part A	
☐ Common Specifications applied: ☒ N/A			
☐ Other Relevant Union Legislation Declared: ☒ N/A			
☐ Class I	☐ Annex II and III		
Technical Documentation Identifier: TOTAL30 (lehfilcon A) Soft Contact Lenses (DU-VC-011) Supersedes (Date): 31-Jul-2023			

Manufacturer:	**Authorized Representative in the European Union**:
Name: Alcon Laboratories, Inc. Address: 6201 South Freeway Fort Worth, Texas 76134-2099 USA SRN: US-MF-000016248	Name: Alcon Laboratories Belgium Address: Lichterveld 3 2870 Puurs-Sint-Amands Belgium SRN: BE-AR-000014721

Device (Trade Name)	Model/FID Catalogue Number	Basic UDI-DI	EMDN Code, Term	Intended purpose
TOTAL30™ spherical soft contact lenses	N/A	038065GMN000223GZ	Q021004 Contact Lenses	Lehfilcon A soft contact lenses act as a refractive medium to focus light rays on the retina to correct vision.
TOTAL30™ for ASTIGMATISM toric soft contact lenses		038065GMN000224H3		
TOTAL30™ MULTIFOCAL soft contact lenses		038065GMN000259HN		

The device(s) covered by this declaration are in conformity with the European Medical Devices Regulation 2017/745 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 MDR 2017/745

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.

TOTAL30 (lehfilcon A) Soft Contact Lenses, DU-VC-011

Notified Body Information: Applicable ☒ Not Applicable ☐

Conformity Assessment Certificate Number(s) including revision number: G10 020895 0396 Rev. 06
Conformity Certificate Validity Period: 13-Dec-2023 to 23-Jun-2027

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	Signature / Date: Brooks, Amy Digitally signed by Brooks, Amy DN: cn=Brooks, Amy, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2023.12.21 10:22:14 -06'00' Name: Amy Brooks Title/Function: Director, GRA Vision Care For and on behalf of Alcon Laboratories Inc.

DECLARATION OF CONFORMITY OF THE MANUFACTURER

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- The validity of certificates issued under Council Directive 93/43/EEC on Medical Devices (MDD) (Directive Certificates) and
- The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Technical File Number: FW-PH-006

Supersedes (Date): 17-Oct-2023

Manufacturer
Name: Alcon Laboratories, Inc.
Address: 6201 South Freeway
Fort Worth
Texas 76134-2099, USA

SRN: US-MF-000016248

Authorized Representative in the European Community:
Name: Alcon Laboratories Belgium
Address: Lichterveld 3
2870 Puurs-Sint-Amands
Belgium

SRN: BE-AR-000014721

Device (Trade Name)	Model/FID Catalogue Number	GMDN Code Term	Risk Class
SYSTANE ORIGINAL Lubricant Eye Drops 3 mL fill / 8 mL bottle 5 mL fill / 8 mL bottle 10 mL fill / 10 mL bottle 15 mL fill / 15 mL bottle	FID 102344	44237 Eye Lubricant	IIa

Alcon as the manufacturer declares under its sole responsibility:

- **For the below listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the Regulation (EU) 2017/745 are met and**
- **The above listed devices and Alcon as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.**
- **Device(s) as listed above continue to comply with MDD, there are no significant changes in the design and intended purpose, and the device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.**

Directive Certificate number: G1 020895 0393 Revision 00
Original expiry date: 26-May-2024
End date of extended validity / transition period: 31-Dec-2028
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 and Date: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Brooks, Amy Digitally signed by Brooks, Amy DN: cn=Brooks, Amy, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2024.03.04 16:56:37 -06'00' Signature: Name/Title/Function: Amy Brooks / Director / GRA Vision Care For and on behalf of Sherri Lakota / Vice President / GRA Vision Care

DECLARATION OF CONFORMITY OF THE MANUFACTURER

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- The validity of certificates issued under Council Directive 93/43/EEC on Medical Devices (MDD) (Directive Certificates) and
- The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Technical File Number: FW-PH-011

Supersedes (Date): 29-Sep-2023

Manufacturer
Name: Alcon Laboratories, Inc.
Address: 6201 South Freeway
Fort Worth
Texas 76134-2099, USA

SRN: US-MF-000016248

Authorized Representative in the European Community:
Name: Alcon Laboratories Belgium
Address: Lichterveld 3
2870 Puurs-Sint-Amands
Belgium

SRN: BE-AR-000014721

Device (Trade Name)[a]	Model/FID Catalogue Number	GMDN Code Term	Risk Class
SYSTANE ULTRA UD Lubricant Eye Drops 0.5 mL fill / 0.8 mL vial 0.5 mL fill / 1.6 mL vial 0.7 mL fill / 1.2 mL vial 0.7 mL fill / 1.6 mL vial (Unit Dose) SYSTANE ULTRA Lubricant Eye Drops 3 mL fill / 11 mL bottle 10 mL fill / 11 mL bottle (Multi-Dose, Preservative-Free)	FID 114473	48082 Contact Lens Wetting Solution	IIb

[a]See page 2 for alternate names

Alcon as the manufacturer declares under its sole responsibility:

- **For the below listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the Regulation (EU) 2017/745 are met and**
- **The above listed devices and Alcon as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.**
- **Device(s) as listed above continue to comply with MDD, there are no significant changes in the design and intended purpose, and the device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.**

Directive Certificate number: G1 020895 0393 Revision 00
Original expiry date: 26-May-2024
End date of extended validity / transition period: 31-Dec-2028

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 and Date: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Brooks, Amy Digitally signed by Brooks, Amy DN: cn=Brooks, Amy, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2024.03.04 16:59:56 -06'00' Signature: Name/Title/Function: Amy Brooks / Director / GRA Vision Care For and on behalf of Sherri Lakota / Vice President / GRA Vision Care

ALTERNATE NAMES
SYSTANE ULTRA Preservative Free Lubricating Eye Drops
SYSTANE ULTRA Preservative-Free Lubricant Eye Drops
SYSTANE ULTRA UD Lubricating Eye Drops
SYSTANE ULTRA Lubricating Eye Drops
SYSTANE ULTRA Hydrating Eye Drops
SYSTANE ULTRA Moisturizing Eye Drops
SYSTANE ULTRA Comfort Eye Drops
SYSTANE ULTRA Multi-Dose Preservative Free Lubricating Eye Drops
SYSTANE ULTRA MDPF Lubricating Eye Drops
SYSTANE ULTRA SP
SYSTANE ULTRA PF
SYSTANE ULTRA sem conservantes

SYSTANE HYDRATION Lubricant Eye Drops FID 121843, FW-PH-013

DECLARATION OF CONFORMITY (EU MDR Annex IV)

Class, Rule	Conformity Assessment Route		
☐ Class III, Rule ...	☐ Annex IX	☐ Annex X + Annex XI	
☒ Class IIb, Rule 16 & Rule 21 Bullet 4	☒ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex IX, Chapters I and III	☐ Annex X + Annex XI
☐ Class IIa, Rule …	☐ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex II and III + Annex XI, Section 10	☐ Annex II and III + Annex XI, Section 18
☐ Class I(s),(m),(r), Rule ...	☐ Annex II and III + Annex IX, Chapters I and III	☐ Annex II and III + Annex XI, Part A	
☐ Class I	☐ Annex II and III		

Technical Documentation Identifier: SYSTANE HYDRATION Lubricant Eye Drops FID 121843 (FW-PH-013)
Supersedes (Date): 31-Jul-2023

Manufacturer	Authorized Representative in the European Community
Name: Alcon Laboratories, Inc. Address: 6201 South Freeway Fort Worth, Texas 76134-2099 USA SRN: US-MF-000016248	Name: Alcon Laboratories Belgium Address: Lichterveld 3 2870 Puurs-Sint-Amands Belgium SRN: BE-AR-000014721

Manufacturing Site(s)

Multi-Dose	Unit Dose
Name: Alcon Research, LLC (ASPEX) Address: 6201 South Freeway Fort Worth, Texas 76134-2099 USA	Name: Kaysersberg Pharmaceuticals (Contract Manufacturer) Address: 23 Avenue Georges Ferrenbach 68240 Kaysersberg France
Name: Alcon Singapore Manufacturing Pte. Ltd. Address: 19 Tuas South Avenue 14 Singapore 637313 Singapore	

Device (Trade Name)	Catalog Number	Basic UDI-DI	EMDN Code, Term	Intended Purpose
SYSTANE HYDRATION Lubricant Eye Drops*	FID 121843	038065GMN000088HK	Q020302 – Ophthalmology, Liquid Fluids	SYSTANE HYDRATION Lubricant Eye Drops is intended to lubricate the eye surface and rewet soft contact lenses (including silicone hydrogel lenses).

*See page 2 for alternate names
UDI-DI List, reference V-RIM-0093665

The device(s) covered by this declaration are in conformity with the European Medical Devices Regulation 2017/745 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 MDR 2017/745

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) including revision number: G10 020895 0396 Rev. 04
Conformity Certificate Validity Period: 18-Aug-2023 to 23-Jun-2027

Notified Body: TÜV SÜD Product Service GmbH
Identification number: 0123
Address: Ridlerstraße 65, 80339 Munich, Germany

Regulations, Directives and Standards Applied: Refer to Chapter 4 of the Technical Documentation

Place of Issue: Alcon Laboratories, Inc. Fort Worth, Texas 76134-2099 USA	Signature/Date: Lakota, Sherri Digitally signed by Lakota, Sherri Date: 2023.09.29 15:09:14 -05'00' Name: Sherri Lakota Title/Function: Vice President, Global Regulatory Affairs—Vision Care For and on behalf of Alcon Laboratories, Inc.

Alternate Names	
SYSTANE HYDRATION Lubricant Eye Drops FID 121843 is also marketed with the following alternate names:	
Unit Dose (UD):	SYSTANE HYDRATION SYSTANE HYDRATION Lubricant Eye Drops SYSTANE HYDRATION Moisture Contacts Eye Drops SYSTANE HYDRATION UD Lubricant Eye Drops SYSTANE HYDRATATION SYSTANE HYDRATACIÓN UD SYSTANE IDRA SYSTANE Ultra Plus Hidratacão UD SYSTANE Ultra Plus Hidratación UD
Multi-Dose Preservative Free (MDPF):	SYSTANE HYDRATION Lubricant Eye Drops SYSTANE HYDRATION MDPF Lubricant Eye Drops SYSTANE Ultra Plus Lubricant Eye Drops SYSTANE Ultra Plus SP SYSTANE HYDRATION PRESERVATIVE-FREE SYSTANE HYDRATION PF

DECLARATION OF CONFORMITY OF THE MANUFACTURER

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- The validity of certificates issued under Council Directive 93/43/EEC on Medical Devices (MDD) (Directive Certificates) and
- The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Technical File Number: FW-PH-018

Supersedes (Date): 15-Feb-2024

Manufacturer
Name: Alcon Laboratories, Inc.
Address: 6201 South Freeway
Fort Worth
Texas 76134-2099, USA

SRN: US-MF-000016248

Authorized Representative in the European Community:
Name: Alcon Laboratories Belgium
Address: Lichterveld 3
2870 Puurs-Sint-Amands
Belgium

SRN: BE-AR-000014721

Device (Trade Name)[a]	Model/FID Catalogue Number	GMDN Code Term	Risk Class
SYSTANE COMPLETE Lubricant Eye Drops 3 mL fill / 11 mL bottle 10 mL fill / 11 mL bottle	FID 122505	44237 Eye Lubricant	IIa

[a]See page 2 for alternate names

Alcon as the manufacturer declares under its sole responsibility:

- **For the below listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the Regulation (EU) 2017/745 are met and**
- **The above listed devices and Alcon as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.**
- **Device(s) as listed above continue to comply with MDD, there are no significant changes in the design and intended purpose, and the device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.**

Directive Certificate number: G1 020895 0393 Revision 00
Original expiry date: 26-May-2024
End date of extended validity / transition period: 31-DEC-2028
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 and Date: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Brooks, Amy Digitally signed by Brooks, Amy DN: cn=Brooks, Amy, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2024.03.04 16:58:37 -06'00' Signature: Name/Title/Function: Amy Brooks / Director / GRA Vision Care For and on behalf of Sherri Lakota / Vice President / GRA Vision Care

ALTERNATE NAMES
SYSTANE COMPLETE Preservative-Free Lubricant Eye Drops
SYSTANE COMPLETE Multi-Dose Preservative Free (MDPF) Lubricant Eye Drops

AOSEPT PLUS with HydraGlyde FID 120947A, FW-VC-004

DECLARATION OF CONFORMITY (EU MDR Annex IV)			
Class, Rule	**Conformity Assessment Route**		
☐ Class III, Rule ...	☐ Annex IX	☐ Annex X + Annex XI	
☒ Class IIb, Rule 16	☒ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex IX, Chapters I and III	☐ Annex X + Annex XI
☐ Class IIa, Rule ...	☐ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex II and III + Annex XI, Section 10	☐ Annex II and III + Annex XI, Section 18
☐ Class I(s),(m),(r), Rule ...	☐ Annex II and III + Annex IX, Chapters I and III	☐ Annex II and III + Annex XI , Part A	
☐ Common Specifications applied: ☒ N/A			
☐ Other Relevant Union Legislation Declared: ☒ N/A			
☐ Class I	☐ Annex II and III		
Technical Documentation Identifier: AOSEPT PLUS with HydraGlyde FID 120947A (FW-VC-004) Supersedes (Date): N/A (Initial Declaration of Conformity for EU MDR)			

Manufacturer:	**Authorized Representative in the European Union**:
Name: Alcon Laboratories, Inc. Address: 6201 South Freeway Fort Worth, Texas 76134-2099 USA SRN: US-MF-000016248	Name: Alcon Laboratories Belgium Address: Lichterveld 3 2870 Puurs-Sint-Amands Belgium SRN: BE-AR-000014721

Device (Trade Name)	Model/FID Catalogue Number	Basic UDI-DI	EMDN Code, Term	Intended purpose
AOSEPT PLUS with HydraGlyde 90 mL/120 mL Bottle 360 mL / 360 mL Bottle 480 mL / 480 mL Bottle	120947A	038065GMN000097HL	Q020302 Ophthalmology, Liquid Fluids	AOSEPT PLUS with HydraGlyde FID 120947A is intended for cleaning, disinfection, and storage of soft contact lenses (including silicone hydrogel lenses) and rigid gas permeable lenses.

The device(s) covered by this declaration are in conformity with the European Medical Devices Regulation 2017/745 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 MDR 2017/745

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) including revision number: G10 020895 0396 Rev. 06
Conformity Certificate Validity Period: 13-Dec-2023 to 23-Jun-2027

Notified Body: TÜV SÜD Product Service GmbH
Identification number: 0123
Address: Ridlerstraße 65, 80339 Munich, Germany

Regulations, Directives and Standards Applied: Refer to Chapter 4 of the Technical Documentation

Place of Issue:	Signature / Date:
Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Brooks, Amy Digitally signed by Brooks, Amy DN: cn=Brooks, Amy, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2024.03.27 10:21:49 -05'00' Name: Amy Brooks Title/Function: Director, GRA Vision Care For and on behalf of Sherri Lakota (Vice President GRA VC & DEOH) and Alcon Laboratories Inc.

Opti-Free PureMoist MPDS FID 114675A, FW-VC-007

DECLARATION OF CONFORMITY (EU MDR Annex IV)			
Class, Rule	**Conformity Assessment Route**		
☐ Class III, Rule ...	☐ Annex IX	☐ Annex X + Annex XI	
☒ Class IIb, Rule 16	☒ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex IX, Chapters I and III	☐ Annex X + Annex XI
☐ Class IIa, Rule ...	☐ Annex IX, Chapters I and III + Annex IX, Section 4	☐ Annex II and III + Annex XI, Section 10	☐ Annex II and III + Annex XI, Section 18
☐ Class I(s),(m),(r), Rule ...	☐ Annex II and III + Annex IX, Chapters I and III	☐ Annex II and III + Annex XI , Part A	
☐ Common Specifications applied: ☒ N/A			
☐ Other Relevant Union Legislation Declared: ☒ N/A			
☐ Class I	☐ Annex II and III		
Technical Documentation Identifier: OPTI-FREE PureMoist Multi-Purpose Disinfecting Solution (MPDS) FID 114675A (FW-VC-007) Supersedes (Date): 21-Dec-2023			

Manufacturer:	**Authorized Representative in the European Union**:
Name: Alcon Laboratories, Inc. Address: 6201 South Freeway Fort Worth, Texas 76134-2099 USA SRN: US-MF-000016248	Name: Alcon Laboratories Belgium Address: Lichterveld 3 2870 Puurs-Sint-Amands Belgium SRN: BE-AR-000014721

Device (Trade Name)	Model/FID Catalogue Number	Basic UDI-DI	EMDN Code, Term	Intended purpose
OPTI-FREE™ PureMoist™ Multi-Purpose Disinfecting Solution (MPDS) 60 mL / 60 mL Bottle 90 mL / 120 mL Bottle 120 mL / 120 mL Bottle 300 mL / 360 mL Bottle 420 mL / 480 mL Bottle	114675A	038065GMN000097HL	Q020302 Ophthalmology, Liquid Fluids	OPTI-FREE PureMoist MPDS FID 114675A is intended for cleaning, disinfection, and storage of soft contact lenses (including silicone hydrogel lenses).

The device(s) covered by this declaration are in conformity with the European Medical Devices Regulation 2017/745 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 MDR 2017/745

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) including revision number: G10 020895 0396 Rev. 06
Conformity Certificate Validity Period: 13-Dec-2023 to 23-Jun-2027

Notified Body: TÜV SÜD Product Service GmbH
Identification number: 0123
Address: Ridlerstraße 65, 80339 Munich, Germany

Regulations, Directives and Standards Applied: Refer to Chapter 4 of the Technical Documentation

Place of Issue: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Signature / Date: Lakota, Sherri Digitally signed by Lakota, Sherri Date: 2024.01.23 14:34:31 -06'00' Name: Sherri Lakota Title/Function: Vice President, GRA Vision Care & DEOH For and on behalf of Alcon Laboratories Inc.