EU Technical File Version 8.0

DECLARATION OF CONFORMITY

Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Product Name	senofilcon C Contact Lenses
Description	Spherical (senofilcon C) contact lenses are intended for Daily Wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may have 1.00D or less of astigmatism. Toric (senofilcon C) contact lenses are intended for Daily Wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may have astigmatism. These lenses contain a UV (ultraviolet) blocker to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.
Product Identification	See page 2 of this Declaration
Classification	IIa
Classification Rationale	Rule 5
Declaration	This declaration of conformity is issued under the sole responsibility of the manufacturer, per Decision No 768/2008/EC. We, being the manufacturer/distributor within the European Economic Area, declare that the products covered by this declaration, documented in Technical File – senofilcon C Version 8.0, dated 22 April 2022, conform with the provisions of the essential requirements and provisions of European Council Directive 93/42/EEC. We, the manufacturer/distributor, have been subject to the conformity procedures laid down in Annex II under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands Competent Authority, carrying the Notified Body Number 2797 and no application has been lodged with any other Notified Body. This declaration is supported by the Johnson & Johnson Vision Care, Inc. (JJVCI) Quality Management Systems approved by EC Certificate for Quality Assurance Certificate Number CE 00387. This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.

CONFIDENTIAL

Manufacturing Sites	This document is valid for all devices described originating from the following site: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Authorized Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin Ireland
Product Names and Models	The following product listing includes Diagnostic, Revenue and Kit Configurations Product Family: • ACUVUE VITA Models: • ACUVUE® VITA® Brand Contact Lenses • ACUVUE® VITA® Brand Contact Lenses for ASTIGMATISM GMDN Codes: 47842, Soft corrective contact lens, daily wear

Victoria Brennand

Digitally signed by Victoria Brennand
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1039331, cn=Victoria Brennand
Reason: I attest to the accuracy and integrity of this document.
Date: 2022.04.22 09:21:05 -04'00'
Adobe Acrobat version: 2020.013.20064

April 22 2022

Victoria Brennand, Ph.D.
Associate Director, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

THOMAS WILKINSON JR

Digitally signed by THOMAS WILKINSON JR
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=175047, cn=THOMAS WILKINSON JR
Reason: I attest to the accuracy and integrity of this document
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Adobe Acrobat Reader version: 2020.013.20064

April 22, 2022

Thomas Wilkinson
Director, Quality Systems, Quality and Compliance
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

Johnson & Johnson VISION

EU DECLARATION OF CONFORMITY

Technical Documentation	senofilcon C contact lenses		
Document ID and Version Number	VIS-REGFLG-020427/1		
Product Identification	**Trade Name of Device** The following product listing includes Diagnostic, Revenue, and Kit Configurations:	**Device Name**	**Basic UDI-DI**
	ACUVUE® VITA® Brand Contact Lenses	ACUVUE VITA	00733905a00007BU
	ACUVUE® VITA® Brand Contact Lenses for Astigmatism		
Legal Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States www.acuvue.com		
EU Authorised Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin D22 X0Y3 Ireland		
Notified Body	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands Phone: +31 (0)20 346 07 80 Notified Body number: 2797		

Intended Purpose	Spherical ACUVUE® VITA® Brand Contact Lenses are intended for Daily Wear for the optical correction of myopia (short sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that may have 1.00D or less of astigmatism. Toric ACUVUE® VITA® Brand Contact Lenses are intended for Daily Wear for the optical correction of myopia (short sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that may have astigmatism. These lenses contain a UV (ultraviolet) blocker to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.
Classification	Class IIa (Annex VIII, Rule 5)
Product Codes	Universal Product Codes (UPC) for the contact lenses are obtained within the ERP (Enterprise Resource Planning) SAP system
GMDN Code(s)	47842, Soft corrective contact lens, daily wear
EMDN Code	Q0210040102, Contact Lenses-Hydrogel, Reusable
Manufacturer's Single Registration Number (SRN)	Not yet available
Authorized Representative Single Registration Number (SRN)	IE-AR-000013513
Common Specifications	N/A
Union Legislation	Other Union Legislation has been evaluated for JJVCI Class IIa products and determined to be not applicable
Design, Manufacturing and Distribution Sites	This document is valid for all medical devices described originating from the following sites: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC The National Technology Park, Limerick V94 N732 Ireland
This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.	
We, Johnson & Johnson Vision Care, Inc., hereby declare the above listed medical devices comply with Medical Device Regulation (MDR) 2017/745. This declaration is made on the basis of MDR Certificate Number 732087, issued by above stated Notified Body, in accordance with the conformity assessment laid down in Annex IX of MDR 2017/745.	

SIGNATURES			
Place of Issue	Refer to Manufacturer's Address above		
Victoria Brennand Digitally signed by Victoria Brennand DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1039331, cn=Victoria Brennand Reason: I am approving this document. Date: 2023.03.07 09:59:33 -05'00' Adobe Acrobat version: 2020.013.20064		Date	Refer to date from electronic signature.
Victoria Brennand Director, Regulatory Affairs Johnson & Johnson Vision Care, Inc. Jacksonville, Florida 32256, USA			
JASON JASPER Digitally signed by JASON JASPER DN: c=US, o=JNJ, ou=Subscribers, cn=JASON JASPER, 0.9.2342.19200300.100.1.1=377178 Reason: I am approving this document Date: 2023.03.07 10:43:56 -05'00' Adobe Acrobat Reader version: 2020.013.20064		Date	Refer to date from electronic signature.
Jason Jasper Senior Manager, Quality Systems Johnson & Johnson Vision Care, Inc. Jacksonville, Florida 32256, USA			

Note: The English DoC is considered the "EN Master DoC". The dated signature present in the "EN Master DoC" will represent the date of validity for any translated DoCs.

Johnson & Johnson VISION

CERTIFICATION OF COPY

On this 20th day of January 2021, I certify that the attached is a true, exact, and unaltered photocopy provided to me of:

- **EC Certificate – Full Quality Assurance System – CE 00387 – 5 pages**

presented to me by Eileen S. Troxell, Regulatory Affairs Specialist I, Regulatory Affairs, and to the best of my knowledge, that the photocopied documents are neither a vital record nor a public record, certified copies of which are available from an official source other than a Notary Public.

United States of America }
State of Florida }
County of Duval }

(Notary Public)

COLLEEN GILMARTIN CANO
Commission # GG 094658
Expires April 16, 2021
Bonded Thru Troy Fain Insurance 800-385-7019

COLLEEN GILMARTIN CANO NOTARY PUBLIC STATE OF FLORIDA

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00387**

Issued To: **Johnson & Johnson Vision Care, Inc.**
7500 Centurion Parkway
Jacksonville
Florida
32256
USA

In respect of:

The design, manufacture and final inspection of sterile soft contact lenses used for refractive correction, as a bandage lens or for the attenuation of bright light.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1994-12-09** Date: **2020-12-15** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 00387

Issued To:

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville
Florida
32256
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MDN 0105	1-DAY ACUVUE MOIST with LACREON	Refractive Vision Correction
	1-DAY ACUVUE DEFINE with LACREON	Refractive Vision Correction
	ACUVUE 2	Refractive Vision Correction
	ACUVUE 2 DEFINE	Refractive Vision Correction
	ACUVUE OASYS with HYDRACLEAR PLUS	Refractive Vision Correction and Bandage Indication
	ACUVUE OASYS with HYDRALUXE	Refractive Vision Correction
	ACUVUE OASYS with TRANSITIONS	Refractive Vision Correction and Attenuation of Bright Light
	ACUVUE VITA	Refractive Vision Correction
	1-DAY ACUVUE TRUEYE	Refractive Vision Correction
	ACUVUE ADVANCE	Refractive Vision Correction

First Issued: **1994-12-09** Date: **2020-12-15** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00387**
Date:	**2020-12-15**
Issued To:	**Johnson & Johnson Vision Care, Inc.** **7500 Centurion Parkway** **Jacksonville** **Florida** **32256** **USA**

Subcontractor:	**Service(s) supplied**
AMO Ireland Block B Liffey Valley Office Campus Quarryvale Co. Dublin D22 X0Y3 Ireland	**EU Representative**
Johnson & Johnson Vision Care European Vision Centre 8 Hanworth Road Sunbury TW16 5LN United Kingdom	**Distribution** **Packaging**
Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 H97W Ireland	**Manufacture** **Moist Heat Sterilization**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00387**
Date:	**2020-12-15**
Issued To:	**Johnson & Johnson Vision Care, Inc.** **7500 Centurion Parkway** **Jacksonville** **Florida** **32256** **USA**

Subcontractor:	**Service(s) supplied**
Johnson & Johnson Vision Care Ireland UC, formerly Johnson & Johnson Vision Care (Ireland) The National Technology Park Limerick V94 N732 Ireland	**Manufacture** **Moist Heat Sterilization**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00387**

Date: **2020-12-15**

Issued To: **Johnson & Johnson Vision Care, Inc.**
7500 Centurion Parkway
Jacksonville
Florida
32256
USA

Date	Reference Number	Action
9 December 1994	-	First issue.
14 October 1996	-	Correction in address, addition of sub-contractor "VISTAKON Ireland".
15 April 1997	-	Change of address, addition of location "5999 Richard Street, Jacksonville, Florida".
12 January 2000	-	Change in company name.
5 May 2000	-	Change in company name.
16 March 2005	-	Renewal of certificate, and scope updated to improve regulatory compliance.
10 February 2006	-	Change on Subcontractors list: removal of location "5999 Richard Street, Jacksonville, Florida".
27 April 2009	7344530	Change of company name from 'Vistakon – Division of Johnson & Johnson Vision Care, Inc' to 'Johnson & Johnson Vision Care, Inc.' Subcontractor name change inline with company name change.
25 November 2009	7296771	Certificate renewal.
18 February 2010	7490261	Addition of sub-contractors Johnson & Johnson Vision Care and Johnson & Johnson Medical Ltd.
12 November 2014	8196416	Certificate renewal.

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00387**

Date: **2020-12-15**

Issued To: **Johnson & Johnson Vision Care, Inc.**
7500 Centurion Parkway
Jacksonville
Florida
32256
USA

Date	Reference Number	Action
12 February 2019	9686447	Review of Transitions Contact Lenses.
19 February 2019	7781187	Traceable to NB 0086.
07 May 2019	9754187	Addition of a second EU representative: AMO Ireland, Co. Dublin D22 X0Y3.
02 December 2019	3078659	Certificate renewal, Clarification of scope.
Current	3313210	Addition of new building at Limerick site. Listing of Irish location as Unlimited company. Addition of product information table. Removal of subcontractor Johnson & Johnson Medical Ltd.

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 732087 R000

Manufacturer: Johnson & Johnson Vision Care, Inc.

Address:
7500 Centurion Parkway
Jacksonville
Florida
32256
USA

Single Registration Number: Not Available

EU Authorised Representative: AMO Ireland

Address:
Block B
Liffey Valley Office Campus
Quarryvale
Co. Dublin
D22 X0Y3
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-10-26**

Current Issue Date: **2023-01-26**

Starting Validity Date: **2023-01-26**

Expiry Date: **2026-10-25**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 732087 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Daily disposable silicone hydrogel contact lenses for refractive vision correction	Class IIa
Daily wear and extended wear silicone hydrogel contact lenses for refractive vision correction and bandage indication.	Class IIa
Daily wear (including daily disposable and reusable wear) and extended wear hydrogel contact lenses for refractive vision correction	Class IIa
Daily wear (including daily disposable and reusable wear) silicone hydrogel contact lenses for refractive vision correction and attenuation of bright light.	Class IIa

First Issue Date: **2021-10-26**

Current Issue Date: **2023-01-26**

Starting Validity Date: **2023-01-26**

Expiry Date: **2026-10-25**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 732087 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-10-26	3254121	Issued
2022-09-16	3731375	Supplemented – Addition of hydrogel devices
Current	3847518	Supplemented – Addition of light attenuation devices

First Issue Date: **2021-10-26**

Current Issue Date: **2023-01-26**

Starting Validity Date: **2023-01-26**

Expiry Date: **2026-10-25**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical File Version 6.0

DECLARATION OF CONFORMITY

Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Product Name	senofilcon A with Photochromic Additive Contact Lenses
Description	Spherical (senofilcon A with Photochromic Additive) contact lenses are intended for the optical correction of refractive ametropia (myopia and hyperopia) in persons with healthy eyes that may have 1.00D or less of astigmatism. These lenses may be prescribed for daily wear. These lenses are also indicated for the attenuation of bright light as they contain a photochromic additive which dynamically absorbs visible light. These lenses contain a UV (ultraviolet) blocker to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.
Product Identification	See page 2 of this Declaration
Classification	IIa
Classification Rationale	Rule 5
Declaration	This declaration of conformity is issued under the sole responsibility of the manufacturer, per Decision No 768/2008/EC. We, being the manufacturer/distributor within the European Economic Area, declare that the product covered by this declaration, documented in the Technical File – senofilcon A with Photochromic Additive Version 6.0, dated 21 December 2022, conform with the essential requirements and provisions of European Council Directive 93/42/EEC. We, the manufacturer/distributor, have been subject to the conformity procedures laid down in Annex II under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands Competent Authority, carrying the Notified Body Number 2797 and no application has been lodged with any other Notified Body. This declaration is supported by the Johnson & Johnson Vision Care, Inc. Quality Management System approved by EC Certificate for Quality Assurance Certificate Number CE 00387. This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.

Manufacturing Sites	This document is valid for all devices described originating from the following sites: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Repackaging and Distribution Sites	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Authorized Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin Ireland
Product Names and Models	The following product listing includes Diagnostic, Revenue and Kit Configurations. ACUVUE® OASYS with Transitions™ GMDN Code: 47844, Visible-light-filtering corrective contact lens

Victoria Brennand

Digitally signed by Victoria Brennand
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Reason: I attest to the accuracy and integrity of this document.
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Adobe Acrobat version: 2020.013.20064

12/21/22

Victoria Brennand
Director, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

JASON JASPER

Digitally signed by JASON JASPER
DN: c=US, o=JNJ, ou=Subscribers, cn=JASON JASPER, 0.9.2342.19200300.100.1.1=377178
Reason: I attest to the accuracy and integrity of this document
Date: 2022.12.22 09:14:13 -05'00'
Adobe Acrobat Reader version: 2020.013.20064

12/22/22

Jason Jasper
Sr. Manager, Quality Systems, Quality Compliance
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

EU Technical File Version 27.1

DECLARATION OF CONFORMITY

Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Product Name	etafilcon A Contact Lenses
Description	The spherical (non-cosmetic tint) etafilcon A contact lenses are intended for Daily Wear or Extended Wear for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that may have 1.00D or less of astigmatism. The spherical cosmetic tint etafilcon A contact lenses are intended for Daily Wear or Extended Wear to alter/enhance the appearance of the eye and for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that have 1.00D or less of astigmatism. The etafilcon A contact lenses for astigmatism (toric) are intended for Daily Wear for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes who may have astigmatism. The etafilcon A contact lenses for presbyopia are intended for Daily Wear for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in presbyopic persons with healthy eyes who have 0.75D or less of astigmatism. All etafilcon A contact lenses have UV blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.
Product Identification	See page 3 of this Declaration
Classification	IIa
Classification Rationale	Rule 5

Declaration	This declaration of conformity is issued under the sole responsibility of the manufacturer, per Decision No 768/2008/EC. We, being the manufacturer/distributor within the European Economic Area, declare that the products covered by this declaration, documented in Technical File - etafilcon A Version 27.1, dated 10 May 2023, conform with the provisions of the essential requirements and provisions of European Council Directive 93/42/EEC. We, the manufacturer/distributor, have been subject to the conformity procedures laid down in Annex II under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands Competent Authority, carrying the Notified Body Number 2797 and no application has been lodged with any other Notified Body. This declaration is supported by the Johnson & Johnson Vision Care, Inc., Quality Management Systems approved by EC Certificate for Quality Assurance Certificate Number CE 00387. This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.
Manufacturing Sites	This document is valid for all devices described originating from the following sites: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC formerly Johnson & Johnson Vision Care (Ireland) The National Technology Park, Limerick V94 N732 Ireland
Repackaging and Distribution Sites	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 N732 Ireland Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 H97W Ireland

Authorized Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin Ireland
Product Names and Models	The following product listing includes Diagnostic, Revenue, and Kit Configurations Legacy Products: • 1-DAY ACUVUE® Brand Contact Lenses • ACUVUE® 2 Brand Contact Lenses Models: • 1-DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® • ACUVUE® 2 DEFINE® Brand Contact Lenses Product Family: • 1-DAY ACUVUE® MOIST with LACREON Models: • 1-DAY ACUVUE® MOIST Brand Contact Lenses with LACREON® • 1-DAY ACUVUE® MOIST Brand Contact Lenses with LACREON® for ASTIGMATISM • 1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses with LACREON® GMDN Codes: 47842 Soft corrective contact lenses, daily-wear 47841 Soft corrective contact lenses, daily-disposable 47843 Soft corrective contact lenses, extended wear

Victoria Brennand

Digitally signed by Victoria Brennand
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1039331, cn=Victoria Brennand
Reason: I attest to the accuracy and integrity of this document.
Date: 2023.05.10 16:08:06 -04'00'
Adobe Acrobat version: 2020.013.20064

5/10/23

Victoria Brennand — Date
Director, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

JASON JASPER

Digitally signed by JASON JASPER
DN: c=US, o=JNJ, ou=Subscribers, cn=JASON JASPER, 0.9.2342.19200300.100.1.1=377178
Reason: I attest to the accuracy and integrity of this document
Date: 2023.05.10 16:10:08 -04'00'
Adobe Acrobat Reader version: 2020.013.20064

5/10/23

Jason Jasper — Date
Senior Manager, Quality Systems, Quality Compliance
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

EU Technical File Version 27.0

DECLARATION OF CONFORMITY

Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Product Name	etafilcon A Contact Lenses
Description	The spherical (non-cosmetic tint) etafilcon A contact lenses are intended for Daily Wear or Extended Wear for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that may have 1.00D or less of astigmatism. The spherical cosmetic tint etafilcon A contact lenses are intended for Daily Wear or Extended Wear to alter/enhance the appearance of the eye and for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that have 1.00D or less of astigmatism. The etafilcon A contact lenses for astigmatism (toric) are intended for Daily Wear for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes who may have astigmatism. The etafilcon A contact lenses for presbyopia are intended for Daily Wear for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in presbyopic persons with healthy eyes who have 0.75D or less of astigmatism. All etafilcon A contact lenses have UV blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.
Product Identification	See page 3 of this Declaration
Classification	IIa
Classification Rationale	Rule 5

Declaration	This declaration of conformity is issued under the sole responsibility of the manufacturer, per Decision No 768/2008/EC. We, being the manufacturer/distributor within the European Economic Area, declare that the products covered by this declaration, documented in Technical File - etafilcon A Version 27.0, dated 12 December 2022, conform with the provisions of the essential requirements and provisions of European Council Directive 93/42/EEC. We, the manufacturer/distributor, have been subject to the conformity procedures laid down in Annex II under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands Competent Authority, carrying the Notified Body Number 2797 and no application has been lodged with any other Notified Body. This declaration is supported by the Johnson & Johnson Vision Care, Inc., Quality Management Systems approved by EC Certificate for Quality Assurance Certificate Number CE 00387. This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.
Manufacturing Sites	This document is valid for all devices described originating from the following sites: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC formerly Johnson & Johnson Vision Care (Ireland) The National Technology Park, Limerick V94 N732 Ireland
Repackaging and Distribution Sites	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 N732 Ireland Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 H97W Ireland

Authorized Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin Ireland
Product Names and Models	The following product listing includes Diagnostic, Revenue, and Kit Configurations Standalone models: • 1-DAY ACUVUE® Brand Contact Lenses • ACUVUE® 2 Brand Contact Lenses • 1-DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® • ACUVUE® 2 DEFINE® Brand Contact Lenses Product Family: • 1-DAY ACUVUE® MOIST with LACREON Models: o 1-DAY ACUVUE® MOIST Brand Contact Lenses with LACREON® o 1-DAY ACUVUE® MOIST Brand Contact Lenses with LACREON® for ASTIGMATISM o 1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses with LACREON® GMDN Codes: 47842 Soft corrective contact lenses, daily-wear 47841 Soft corrective contact lenses, daily-disposable 47843 Soft corrective contact lenses, extended wear

Victoria Brennand

Digitally signed by Victoria Brennand
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1039331, cn=Victoria Brennand
Reason: I attest to the accuracy and integrity of this document.
Date: 2022.12.12 14:12:44 -05'00'
Adobe Acrobat version: 2020.013.20064

12/12/22

Victoria Brennand
Director, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

JASON JASPER

Digitally signed by JASON JASPER
DN: c=US, o=JNJ, ou=Subscribers, cn=JASON JASPER, 0.9.2342.19200300.100.1.1=377178
Reason: I attest to the accuracy and integrity of this document
Date: 2022.12.12 14:26:21 -05'00'
Adobe Acrobat Reader version: 2020.013.20064

12/12/22

Jason Jasper
Senior Manager, Quality Systems, Quality Compliance
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

EU Technical File Version 25.0

DECLARATION OF CONFORMITY

Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Product Name	galyfilcon A Contact Lenses
Description	Spherical (galyfilcon A) contact lenses are intended for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less. Toric (galyfilcon A) contact lenses are intended for daily wear for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes who are hyperopic or myopic and may have 0.50D to 2.50D of astigmatism. The galyfilcon A contact lenses contain a UV (ultraviolet) blocker to help provide protection against the transmission of harmful UV radiation to the cornea and into the eye.
Product Identification	See page 2 of this Declaration
Classification	IIa
Classification Rationale	Rule 5
Declaration	This declaration of conformity is issued under the sole responsibility of the manufacturer, per Decision No 768/2008/EC. We, being the manufacturer/ distributor within the European Economic Area, declare that the products covered by this declaration, documented in Technical File –galyfilcon A Version 25.0, dated 18 November 2021, conform with the provisions of the essential requirements and provisions of European Council Directive 93/42/EEC. We, the manufacturer/distributor, have been subject to the conformity procedures laid down in Annex II under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands Competent Authority, carrying the Notified Body Number 2797 and no application has been lodged with any other Notified Body. This declaration is supported by the Johnson & Johnson Vision Care, Inc. (JJVCI) Quality Management Systems approved by EC Certificate for Quality Assurance Certificate Number CE 00387. This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.

Manufacturing Sites	This document is valid for all devices described originating from the following site: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care (Ireland) The National Technology Park, Limerick V94 N732 Ireland
Repackaging and Distribution Sites	Johnson & Johnson Vision Care European Vision Centre 8 Hanworth Road Sunbury TW16 5LN United Kingdom
Authorized Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin Ireland
Product Names and Models: (galyfilcon A)	Product listing includes Diagnostic, Revenue and Kit Configurations ACUVUE® ADVANCE Brand Contact Lenses with HYDRACLEAR® ACUVUE® ADVANCE Brand Contact Lenses for ASTIGMATISM ACUVUE® ADVANCE Plus Brand Contact Lenses GMDN Code: 47842 Soft corrective contact lenses, daily wear

Victoria Brennand

Digitally signed by Victoria Brennand
Date: 2021.11.18 16:09:33 -05'00'

November 18 2021

Victoria Brennand
Associate Director, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

THOMAS WILKINSON JR

Digitally signed by THOMAS WILKINSON JR
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=175047, cn=THOMAS WILKINSON JR
Reason: I attest to the accuracy and integrity of this document
Date: 2021.11.19 08:27:58 -05'00'
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November 19, 2021

Thomas Wilkinson
Director, Quality Systems, Quality Compliance
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

EU Technical File Version 17.0

DECLARATION OF CONFORMITY

Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Product Name	narafilcon A Contact Lenses
Description	Spherical (narafilcon A) contact lenses are intended for daily wear single use only, for the optical correction of myopia and hyperopia in persons with healthy eyes that may have 1.00D or less of astigmatism. The narafilcon A contact lenses contain a UV (ultraviolet) blocker to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.
Product Identification	See page 2 of this Declaration
Classification	IIa
Classification Rationale	Rule 5
Declaration	This declaration of conformity is issued under the sole responsibility of the manufacturer, per Decision No 768/2008/EC. We, being the manufacturer/distributor within the European Economic Area, declare that the products covered by this declaration, documented in Technical File -narafilcon A Version 17.0, dated 15 December 2022, conform with the essential requirements and provisions of European Council Directive 93/42/EEC. We, the manufacturer/distributor, have been subject to the conformity procedures laid down in Annex II under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands Competent Authority, carrying the Notified Body Number 2797 and no application has been lodged with any other Notified Body. This declaration is supported by the Johnson & Johnson Vision Care, Inc. (JJVCI) Quality Management Systems approved by EC Certificate for Quality Assurance Certificate Number CE 00387. This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.

Manufacturing Sites	This document is valid for all devices described originating from the following sites: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland Unlimited Company, formerly Johnson & Johnson Vision Care (Ireland) The National Technology Park Limerick V94 N732 Ireland **Note:** Legal entity name change from Johnson & Johnson Vision Care (Ireland) to Johnson & Johnson Vision Care Ireland Unlimited Company to comply with Irish Law Companies Act 2014.
Repackaging and Distribution Sites	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 N732 Ireland Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 H97W Ireland
Authorized Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin Ireland
Product Name and Model: (narafilcon A)	Product listing includes Diagnostic, Revenue Configurations 1-DAY ACUVUE® TruEye® Brand Contact Lenses with HYDRACLEAR® 1 GMDN Code: 47841, Soft corrective contact lens, daily-disposable

Victoria Brennand

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Reason: I attest to the accuracy and integrity of this document.
Date: 2022.12.15 15:46:51 -05'00'
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12/15/22

Victoria Brennand
Director, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

JASON JASPER

Digitally signed by JASON JASPER
DN: c=US, o=JNJ, ou=Subscribers, cn=JASON JASPER, 0.9.2342.19200300.100.1.1=377178
Reason: I attest to the accuracy and integrity of this document
Date: 2022.12.15 15:43:13 -05'00'
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12/15/22

Jason Jasper
Senior Manager, Quality Systems, Quality Compliance
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

EU Technical File Version 31.0

DECLARATION OF CONFORMITY

Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Product Name	senofilcon A Contact Lenses
Description	Spherical (senofilcon A) contact lenses are intended for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that may have 1.00D or less of astigmatism. The lenses may be prescribed for either daily wear or extended wear. Multifocal (senofilcon A) lenses are intended for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in presbyopic persons with healthy eyes who have 0.75D or less of astigmatism. The lenses may be prescribed for either daily wear or extended wear. Toric (senofilcon A) contact lenses are intended for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that may have astigmatism. The lenses may be prescribed for either daily wear or extended wear. The senofilcon A contact lenses contain a UV (ultraviolet) blocker to help provide protection against transmission of harmful UV radiation to the cornea and into the eye. All lens designs within the ACUVUE® OASYS with HYDRACLEAR® PLUS product family are also indicated for therapeutic use as a bandage lens for certain ocular conditions.
Product Identification	See page 2 of this Declaration
Classification	IIa
Classification Rationale	Rule 5

CONFIDENTIAL

Declaration	This declaration of conformity is issued under the sole responsibility of the manufacturer, per Decision No 768/2008/EC. We, being the manufacturer/distributor within the European Economic Area, declare that the products covered by this declaration, documented in Technical File – senofilcon A Version 31.0, dated 21 December 2022, conform with the essential requirements and provisions of European Council Directive 93/42/EEC. We, the manufacturer/distributor, have been subject to the conformity procedures laid down in Annex II under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands Competent Authority, carrying the Notified Body Number 2797 and no application has been lodged with any other Notified Body. This declaration is supported by the Johnson & Johnson Vision Care, Inc. (JJVCI) Quality Management Systems approved by EC Certificate for Quality Assurance Certificate Number CE 00387. This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.
Manufacturing Sites	This document is valid for all devices described originating from the following sites: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC, formerly Johnson & Johnson Vision Care (Ireland) The National Technology Park, Limerick V94 N732 Ireland

Repackaging and Distribution Sites	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 N732 Ireland Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 H97W Ireland
Authorized Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin Ireland
Product Names and Models	The following product listing includes Diagnostic, Revenue and Kit Configurations Product Family: • ACUVUE OASYS with HYDRACLEAR PLUS Models: • ACUVUE® OASYS Brand Contact Lenses with HYDRACLEAR® PLUS • ACUVUE® OASYS Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS • ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS • ACUVUE® OASYS MULTIFOCAL Contact Lenses Product Family: • ACUVUE OASYS with HydraLuxe Models: • ACUVUE® OASYS Brand Contact Lenses with HydraLuxe® • ACUVUE® OASYS Brand Contact Lenses with HydraLuxe® for ASTIGMATISM GMDN Codes: 47842, Soft corrective contact lens, daily wear 47843, Soft corrective contact lens, extended wear 36054, Therapeutic contact lens (bandage lens) 47841, Soft corrective contact lens, daily-disposable

Victoria Brennand

Digitally signed by Victoria Brennand
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Reason: I attest to the accuracy and integrity of this document.
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12/21/22

Victoria Brennand
Director, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

JASON JASPER

Digitally signed by JASON JASPER
DN: c=US, o=JNJ, ou=Subscribers, cn=JASON JASPER, 0.9.2342.19200300.100.1.1=377178
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Date: 2022.12.22 09:11:45 -05'00'
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12/22/22

Jason Jasper
Sr. Manager, Quality Systems
Johnson & Johnson Vision Care, Inc.
Jacksonville, Florida 32256, USA

Date

EU Declaration of Conformity

Technical Documentation Name	senofilcon A with Light Filtering Additive contact lenses		
Version Number	VIS-REGFLG-021265/3 v. 2.1		
Product Identification	Trade Name of Device The following product listing includes Diagnostic, Revenue, and Kit Configurations:	Device Name	Basic UDI-DI
	ACUVUE® OASYS MAX 1-Day Contact Lenses	ACUVUE OASYS MAX 1-DAY	0733905a00011BK
	ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses		
Legal Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States www.acuvue.com		
EU Authorised Representative	AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin D22 X0Y3, Ireland		
Notified Body	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands Phone : +31 (0)20 346 07 80 Notified Body number : 2797		

Intended Purpose	The ACUVUE® OASYS MAX 1-Day Contact Lenses are intended for Daily Wear for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in persons with healthy eyes that may have 1.00D or less of astigmatism. The ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses are intended for Daily Wear for the optical correction of myopia (short-sightedness) and hyperopia (long-sightedness) in presbyopic persons with healthy eyes that may have 0.75D or less of astigmatism. The contact lenses contain a UV blocker to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.
Classification	IIa
Product Codes	Universal Product Codes (UPC) for the contact lenses are provided within the ERP (Enterprise Resource Planning) SAP system.
GMDN Code	47841, Soft corrective contact lens, daily-disposable
EMDN Code	Q021004010101, Contact lenses-Hydrogel, Daily Single-Use
Manufacturer's Single Registration Number (SRN)	Not Yet Available
Authorized Representative Single Registration Number (SRN)	IE-AR-000013513
Design, Manufacturing and Distribution Sites	This document is valid for all medical devices described originating from the following sites: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States Johnson & Johnson Vision Care Ireland UC The National Technology Park Limerick V94 N732 Ireland
This Declaration of Conformity is issued under the sole responsibility of the manufacturer.	
We, Johnson & Johnson Vision Care, Inc., hereby declare the above listed medical devices comply with Medical Device Regulation (MDR) 2017/745. This declaration is made on the basis of MDR Certificate Number 732087, issued by above stated Notified Body, in accordance with the conformity assessment laid down in Annex IX of MDR 2017/745.	

SIGNATURES			
Place of Issue	Refer to Manufacturer's Address above		
Victoria Brennand Digitally signed by Victoria Brennand DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1039331, cn=Victoria Brennand Reason: I attest to the accuracy and integrity of this document. Date: 2022.11.09 09:17:43 -05'00' Adobe Acrobat version: 2020.013.20064		**Date**	Refer to date from electronic signature.
Victoria Brennand Director, Regulatory Affairs Johnson & Johnson Vision Care, Inc. Jacksonville, Florida 32256, USA			
THOMAS WILKINSON JR Digitally signed by THOMAS WILKINSON JR DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=175047, cn=THOMAS WILKINSON JR Reason: I attest to the accuracy and integrity of this document Date: 2022.11.09 10:05:05 -05'00' Adobe Acrobat Reader version: 2020.013.20064		**Date**	Refer to date from electronic signature.
Thomas Wilkinson Director, Quality Systems, Quality Compliance Johnson & Johnson Vision Care, Inc. Jacksonville, Florida 32256, USA			