

# Johnson & Johnson VISION

## CERTIFICATION OF COPY

On this 3<sup>rd</sup> day of April 2019, I certify that the attached is a true, exact and unaltered photocopy provided to me of:

- **Declaration of Conformity – senofilcon A – Version 27.0 – 3 pages**

presented to me by Rosalind D. Williams, Project Leader, 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)





VISION CARE, INC.

EU Technical File Version 27.0

## DECLARATION OF CONFORMITY

<b>Manufacturer</b>	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
<b>Product Name</b>	senofilcon A Contact Lenses
<b>Description</b>	<p>Spherical contact lenses are intended for Daily Wear or Extended 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.</p> <p>Multifocal lenses are intended for Daily Wear or Extended Wear for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who have 0.75D or less of astigmatism.</p> <p>Toric contact lenses are intended for Daily Wear or Extended Wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may have astigmatism.</p> <p>The senofilcon A contact lenses have UV Blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.</p> <p>The contact lens is also indicated for therapeutic use as a bandage lens for certain ocular conditions.</p>
<b>Product Identification</b>	See page 2 of this Declaration
<b>Classification</b>	IIa
<b>Classification Rationale</b>	Rule 5
<b>Declaration</b>	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 27.0, dated 26 March 2019, conform with the essential requirements and provisions of European Council Directive 93/42/EEC.

**senofilcon A**  
**EU Technical File Version 27.0 – Declaration of Conformity**  
**Johnson & Johnson Vision Care, Inc. (JJVCI)**

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	<p>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.</p> <p>This declaration is supported by the Johnson &amp; Johnson Vision Care, Inc. Quality Management Systems approved by EC Certificate for Quality Assurance Certificate Number CE 00387.</p>
<b>Manufacturing Sites</b>	<p>This document is valid for all devices described originating from the following sites:</p> <p>Johnson &amp; Johnson Vision Care (Ireland) The National Technology Park, Limerick, Ireland</p> <p>Johnson &amp; Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States</p>
<b>Repackaging and Distribution Sites</b>	<p>Johnson &amp; Johnson Vision Care European Vision Centre 8 Hanworth Road Sunbury TW16 5LN United Kingdom</p>
<b>Authorized Representative</b>	<p>AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin D22 X0Y3 Ireland</p>

senofilcon A  
EU Technical File Version 27.0 – Declaration of Conformity  
Johnson & Johnson Vision Care, Inc. (JJVCI)

<b>Product Names and Models: (senofilcon A)</b>	The following are included: Product Family: <ul style="list-style-type: none"><li>• ACUVUE OASYS®</li></ul> Models: <ul style="list-style-type: none"><li>• ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS</li><li>• ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS</li><li>• ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS</li><li>• ACUVUE OASYS® Brand Contact Lenses with HydraLuxe™</li><li>• ACUVUE OASYS® Brand Contact Lenses with HydraLuxe™ for ASTIGMATISM</li></ul> Product Listing includes Diagnostic, Revenue and Kit Configurations. 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
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*Catherine Dillon*

Catherine Dillon  
Director, Regulatory Affairs  
Johnson & Johnson Vision Care, Inc.  
Jacksonville, Florida 32256, USA

*26 March 2019*

Date

*Thomas Wilkinson*

Thomas Wilkinson  
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*26 March 2019*

Date