

# 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

|                                 |   |
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| <b>Manufacturer</b>             | Johnson & Johnson Vision Care, Inc.<br>7500 Centurion Parkway<br>Jacksonville, Florida 32256<br>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)<br/>The National Technology Park,<br/>Limerick, Ireland</p> <p>Johnson &amp; Johnson Vision Care, Inc.<br/>7500 Centurion Parkway<br/>Jacksonville, Florida 32256<br/>United States</p>  |
| <b>Repackaging and Distribution Sites</b> | <p>Johnson &amp; Johnson Vision Care<br/>European Vision Centre<br/>8 Hanworth Road<br/>Sunbury<br/>TW16 5LN<br/>United Kingdom</p>   |
| <b>Authorized Representative</b>          | <p>AMO Ireland<br/>Block B,<br/>Liffey Valley Office Campus,<br/>Quarryvale, Co.<br/>Dublin D22 X0Y3<br/>Ireland</p>  |

senofilcon A  
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Johnson & Johnson Vision Care, Inc. (JJVCI)

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| <b>Product Names and Models: (senofilcon A)</b> | The following are included:<br>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.<br>GMDN Codes: 47842, Soft corrective contact lens, daily wear<br>47843, Soft corrective contact lens, extended wear<br>36054, Therapeutic contact lens (bandage lens)<br>47841, Soft corrective contact lens, daily-disposable |
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*Catherine Dillon*

Catherine Dillon  
Director, Regulatory Affairs  
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Jacksonville, Florida 32256, USA

*26 March 2019*

Date

*Thomas Wilkinson*

Thomas Wilkinson  
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*26 March 2019*

Date