

# Johnson & Johnson VISION

## CERTIFICATION OF COPY

On this 29<sup>th</sup> day of March 2019, I certify that the attached is a true, exact and unaltered photocopy provided to me of:

- **Declaration of Conformity – senofilcon C – Version 5.0 – 2 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 5.0

### DECLARATION OF CONFORMITY

|                                 |  |
|---------------------------------|--|
| <b>Manufacturer</b>             | Johnson & Johnson Vision Care, Inc.<br>7500 Centurion Parkway<br>Jacksonville, Florida 32256<br>United States  |
| <b>Product Name</b>             | senofilcon C Contact Lenses  |
| <b>Description</b>              | <p>Spherical 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.</p> <p>Toric 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.</p> <p>These lenses have UV Blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.</p>  |
| <b>Product Identification</b>   | See page 2 of this Declaration   |
| <b>Classification</b>           | IIa  |
| <b>Classification Rationale</b> | Rule 5   |
| <b>Declaration</b>              | <p>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 5.0, dated 26 March 2019, conform with the essential requirements and provisions of European Council Directive 93/42/EEC.</p> <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> |

senofilcon C  
EU Technical File Version 5.0 – Declaration of Conformity  
Johnson & Johnson Vision Care, Inc. (JJVCI)

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| <b>Manufacturing Sites</b>                      | This document is valid for all devices described originating from the following sites:<br>Johnson & Johnson Vision Care, Inc.<br>7500 Centurion Parkway<br>Jacksonville, Florida 32256<br>United States  |
| <b>Repackaging and Distribution Sites</b>       | Johnson & Johnson Vision Care<br>European Vision Centre<br>8 Hanworth Road<br>Sunbury<br>TW16 5LN<br>United Kingdom  |
| <b>Authorized Representative</b>                | AMO Ireland<br>Block B,<br>Liffey Valley Office Campus,<br>Quarryvale, Co.<br>Dublin D22 X0Y3<br>Ireland   |
| <b>Product Names and Models: (senofilcon C)</b> | The following are included:<br>Product Family: <ul style="list-style-type: none"><li>• ACUVUE® VITA™</li></ul> Models: <ul style="list-style-type: none"><li>• ACUVUE® VITA™ Brand Contact Lenses</li><li>• ACUVUE® VITA™ Brand Contact Lenses for ASTIGMATISM</li></ul> Product Listing includes Diagnostic, Revenue and Kit Configurations.<br><br>GMDN Codes: 47842, Soft corrective contact lens, daily wear |

*Catherine Dillon*

Catherine Dillon  
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*26 March 2019*

Date

*Thomas Wilkinson*

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*26 March 2019*

Date