

Johnson & Johnson VISION

CERTIFICATION OF COPY

On this 29th 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

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| Manufacturer | Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States |
| Product Name | senofilcon C Contact Lenses |
| Description | <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> |
| Product Identification | See page 2 of this Declaration |
| Classification | IIa |
| Classification Rationale | Rule 5 |
| Declaration | <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 & 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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| 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 European Vision Centre 8 Hanworth Road Sunbury TW16 5LN United Kingdom |
| Authorized Representative | AMO Ireland Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin D22 X0Y3 Ireland |
| Product Names and Models: (senofilcon C) | The following are included: Product Family: <ul style="list-style-type: none">• ACUVUE® VITA™ Models: <ul style="list-style-type: none">• ACUVUE® VITA™ Brand Contact Lenses• ACUVUE® VITA™ Brand Contact Lenses for ASTIGMATISM Product Listing includes Diagnostic, Revenue and Kit Configurations. GMDN Codes: 47842, Soft corrective contact lens, daily wear |

Catherine Dillon

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

26 March 2019

Date

Thomas Wilkinson

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

26 March 2019

Date