

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 A with Photochromic Additive – Version 2.0 – 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)





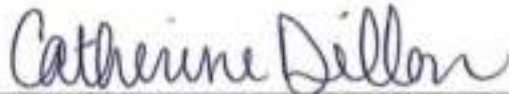
EU Technical File Version 2.0

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	<p>Spherical contact lenses 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>These lenses are also indicated for the attenuation of bright light as they contain a photochromic additive which dynamically absorbs visible light.</p> <p>These lenses contain a UV Blocker to help protect 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 the Technical File – senofilcon A with Photochromic Additive Version 2.0, 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 A with Photochromic Additive
EU Technical File Version 2.0 – Declaration of Conformity
Johnson & Johnson Vision Care, Inc. (JJVCI)

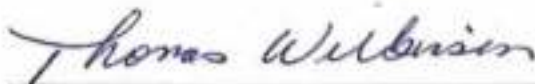
Manufacturing Sites	This document is valid for all devices described originating from the following sites: Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Repackaging and Distribution Sites	Johnson & Johnson Vision Care European Vision Centre 8 Hanworth 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 A with Photochromic Additive)	ACUVUE® OASYS with Transitions™ Product Listing includes Diagnostic, Revenue and Kit Configurations. GMDN Code: 47844, Visible-light-filtering corrective contact lens



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



Date



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



Date