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)

COLLEEN GILMARTIN CANO
Commission # GG 094658
Expires April 16, 2021
Bonded Thru Troy Fain Insurance 800-385-7019

NOTARY PUBLIC

Johnson & Johnson VISION

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	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. These lenses are also indicated for the attenuation of bright light as they contain a photochromic additive which dynamically absorbs visible light. These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye
Product Identification	See page 2 of this Declaration
Classification	IIa
Classification Rationale	Rule 5
Declaration	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. 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. 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.

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

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