Johnson Johnson VISION

CERTIFICATION OF COPY

On this 3rd 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	Į,
County of Duval	

(Notary Public)

KATHLEEN GALLAGHER
Commission # GG 284356
Expires October 2, 2022
Bonded Thru Troy Fein Insurance 800-385-T019



VISION CARE, INC.

EU Technical File Version 27.0

DECLARATION OF CONFORMITY

Manufacturer	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
Product Name	senofilcon A Contact Lenses
Description	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. 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. 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. 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. The contact lens is also indicated for therapeutic use as a bandage
	lens for certain ocular conditions.
Product Identification	See page 2 of this Declaration
Classification	На
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 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)

	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 (Ireland) The National Technology Park, Limerick, Ireland 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

senofilcon A EU Technical File Version 27.0 – Declaration of Conformity Johnson & Johnson Vision Care, Inc. (JJVCI)

Product Names and Models: (senofilcon A)	The following are included:
	Product Family: • ACUVUE OASYS®
	Models:
	ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS
	 ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS
	 ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS
	 ACUVUE OASYS® Brand Contact Lenses with HydraLuxe®
	 ACUVUE OASYS[®] Brand Contact Lenses with HydraLuxe[™] for ASTIGMATISM
	Product Listing includes Diagnostic, Revenue and Kit Configurations.
	GMDN Codes: 47842, Soft corrective contact lens, daily wear
	47843, Soft corrective contact lens, extended wear
	36054, Therapeutic contact lens (bandage lens)
	47841, Soft corrective contact lens, daily-disposable

Catherine Dillon
Director, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.

Johnson & Johnson Vision Care, Inc. Jacksonville, Florida 32256, USA

Thonas Wilbensin

Thomas Wilkinson Director, Quality Systems Johnson & Johnson Vision Care, Inc.

Jacksonville, Florida 32256, USA

26 March 2019

26 Harch 2019

Date