# Johnson & Johnson VISION

#### CERTIFICATION OF COPY

On this 3<sup>rd</sup> day of April 2019, I certify that the attached is a true, exact and unaltered photocopy provided to me of:

Declaration of Conformity – etafilcon 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	
County of Duval	

KATHLEEN GALLAGHER
Commission # GG 264356
Expires October 2, 2022



VISION CARE, INC.

#### EU Technical File Version 24.0

## DECLARATION OF CONFORMITY

Spherical (etafilcon A) contact lenses for the correction of refractive ametropia (myopia, hyperopia or presbyopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less. The lenses may be prescribed for either daily wear or extended wear. Spherical cosmetic tint (etafilcon A) contact lenses also alter/enhance the appearance of the eye. The lenses may be prescribed for either daily wear or extended wear.  Multifocal contact lenses for the correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less. The lenses may be prescribed for either
ametropia (myopia, hyperopia or presbyopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less. The lenses may be prescribed for either daily wear or extended wear. Spherical cosmetic tint (etafilcon A) contact lenses also alter/enhance the appearance of the eye. The lenses may be prescribed for either daily wear or extended wear.  Multifocal contact lenses for the correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 0,75D of astigmatism or less. The lenses may be prescribed for either
daily wear or extended wear.  Toric contact lenses for the correction of visual acuity in phakic or aphakic persons with non-diseased eyes who are hyperopic or myopic and may have 0.50D to 2.50D of astigmatism. The lenses may be prescribed for either daily wear or extended wear.  The etafilcon A contact lenses contain a UV (ultraviolet) blocker to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.
See page 3 of this Declaration
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Rule 5
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 - etafilcon A Version 24.0, 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.

# etafilcon A EU Technical File Version 24.0 – Declaration of Conformity Johnson & Johnson Vision Care, Inc. (JJVCI)

	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
	Johnson & Johnson Vision Care (Ireland)
	The National Technology Park,
	Limerick, Ireland
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

## etafilcon A EU Technical File Version 24.0 – Declaration of Conformity Johnson & Johnson Vision Care, Inc. (JJVCI)

### Product Names and Models:

The following product listing includes Diagnostic, Revenue, and Kit Configurations

#### Legacy Products:

- 1-DAY ACUVUE® Brand Contact Lenses
- ACUVUE® Brand Contact Lenses
- ACUVUE® 2 Brand Contact Lenses
- SUREVUE<sup>TM</sup> Brand Contact Lenses

#### Product Family:

ACUVUE® MOIST

#### Models:

- 1-DAY ACUVUE<sup>®</sup> MOIST Brand Contact Lenses with LACREON<sup>®</sup>
- 1-DAY ACUVUE® MOIST Brand Contact Lenses with LACREON® for ASTIGMATISM
- 1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses with LACREON®

#### Product Family:

ACUVUE® DEFINE®

#### Models:

- 1-DAY ACUVUE® DEFINE® Brand Contact Lenses
- 1-DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON®
- ACUVUE® 2 DEFINE® Brand Contact Lenses

GMDN Codes: 47842 Soft corrective contact lenses, daily-wear

47841 Soft corrective contact lenses, daily-disposable 47843 Soft corrective contact lenses, extended-wear

Catherine Dellon

Catherine Dillon

Director, Regulatory Affairs

Johnson & Johnson Vision Care, Inc.

Jacksonville, Florida 32256, USA

25,255

Thomas Wilkinson

Director, Quality Systems

Johnson & Johnson Vision Care, Inc.

Jacksonville, Florida 32256, USA

Date

26 Harch 2019