

# 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                )

  
(Notary Public)





VISION CARE, INC.

EU Technical File Version 24.0

## DECLARATION OF CONFORMITY

<b>Manufacturer</b>	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, Florida 32256 United States
<b>Product Name</b>	etafilcon A Contact Lenses
<b>Description</b>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
<b>Product Identification</b>	See page 3 of this Declaration
<b>Classification</b>	IIa
<b>Classification Rationale</b>	Rule 5
<b>Declaration</b>	<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 - etafilcon A Version 24.0, 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 &amp; Johnson Vision Care, Inc., Quality Management Systems approved by EC Certificate for Quality</p>

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

---

	Assurance Certificate Number CE 00387.
<b>Manufacturing Sites</b>	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
<b>Repackaging and Distribution Sites</b>	Johnson & Johnson Vision Care European Vision Centre 8 Hanworth Road Sunbury TW16 5LN United Kingdom
<b>Authorized Representative</b>	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)**

<b>Product Names and Models:</b>	The following product listing includes Diagnostic, Revenue, and Kit Configurations.  Legacy Products: <ul style="list-style-type: none"><li>• 1-DAY ACUVUE® Brand Contact Lenses</li><li>• ACUVUE® Brand Contact Lenses</li><li>• ACUVUE® 2 Brand Contact Lenses</li><li>• SUREVUE™ Brand Contact Lenses</li></ul> Product Family: <ul style="list-style-type: none"><li>• ACUVUE® MOIST</li></ul> Models: <ul style="list-style-type: none"><li>• 1-DAY ACUVUE® MOIST Brand Contact Lenses with LACREON®</li><li>• 1-DAY ACUVUE® MOIST Brand Contact Lenses with LACREON® for ASTIGMATISM</li><li>• 1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses with LACREON®</li></ul> Product Family: <ul style="list-style-type: none"><li>• ACUVUE® DEFINE®</li></ul> Models: <ul style="list-style-type: none"><li>• 1-DAY ACUVUE® DEFINE® Brand Contact Lenses</li><li>• 1-DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON®</li><li>• ACUVUE® 2 DEFINE® Brand Contact Lenses</li></ul> GMDN Codes: 47842 Soft corrective contact lenses, daily-wear 47841 Soft corrective contact lenses, daily-disposable 47843 Soft corrective contact lenses, extended-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