

# 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.<br>7500 Centurion Parkway<br>Jacksonville, Florida 32256<br>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)**

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|   | Assurance Certificate Number CE 00387.   |
| <b>Manufacturing Sites</b>                | This document is valid for all devices described originating from the following sites:<br><br>Johnson & Johnson Vision Care, Inc.<br>7500 Centurion Parkway<br>Jacksonville, Florida 32256<br>United States<br><br>Johnson & Johnson Vision Care (Ireland)<br>The National Technology Park,<br>Limerick, Ireland |
| <b>Repackaging and Distribution Sites</b> | Johnson & Johnson Vision Care<br>European Vision Centre<br>8 Hanworth Road<br>Sunbury<br>TW16 5LN<br>United Kingdom  |
| <b>Authorized Representative</b>          | AMO Ireland<br>Block B,<br>Liffey Valley Office Campus,<br>Quarryvale, Co.<br>Dublin D22 X0Y3<br>Ireland   |

**etafilcon A**  
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**Johnson & Johnson Vision Care, Inc. (JJVCI)**

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| <b>Product Names and Models:</b> | The following product listing includes Diagnostic, Revenue, and Kit Configurations.<br><br>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<br>47841 Soft corrective contact lenses, daily-disposable<br>47843 Soft corrective contact lenses, extended-wear |
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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.  
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Date