



DECLARATION OF CONFORMITY

Manufacturer:

AMO Ireland
 Block B
 Liffey Valley Office Campus
 Quarryvale
 D22 XOY3 Co. Dublin
 IRELAND

Manufacturer Production Facility:

AMO Hangzhou, Co. Ltd.
 200, 4th Avenue
 Hangzhou Economic & Technological
 Development Zone, 310018
 Hangzhou, Zhejiang
 PEOPLE’S REPUBLIC of CHINA

<i>Devices Concerned</i>																
Catalog Number/Model Number	Product Name	Device Classification														
<p>Applicable SKU:</p> <p><u>Complete RevitaLens</u> 93686NRH, 93686UFH, 93686RHH, 93686KZH, 93686SAH, 93751EQH, 93751RWH, 93752RYH, 93752RRH, 93744AXH, 93744FLH, 93744GMH, 93744EJH, 93744RWH, 93744RYH, 93745AXH, 93745GMH, 93822GMH, 93823GMH, 93756GMH, 93755RRH, 94012RH, and 94012FL</p> <p><u>ACUVUE RevitaLens:</u></p> <table border="1"> <thead> <tr> <th>SKU Ranges</th> <th>Bottle Size</th> </tr> </thead> <tbody> <tr> <td>94323XX</td> <td>60mL Bottle Size</td> </tr> <tr> <td>94324XX</td> <td>100mL Bottle Size</td> </tr> <tr> <td>94325XX</td> <td>300mL Bottle Size</td> </tr> <tr> <td>94327XX</td> <td>2x300mL Bottle Size</td> </tr> <tr> <td>94326XX</td> <td>360mL Bottle Size</td> </tr> <tr> <td>94329XX</td> <td>3x360mL Bottle Size</td> </tr> </tbody> </table> <p>Note: ACUVUE RevitaLens SKUs are representative of SKU ranges. The last two letters of the SKUs are specific to the country of destination with the only difference relating to the language translations on the labels.</p>	SKU Ranges	Bottle Size	94323XX	60mL Bottle Size	94324XX	100mL Bottle Size	94325XX	300mL Bottle Size	94327XX	2x300mL Bottle Size	94326XX	360mL Bottle Size	94329XX	3x360mL Bottle Size	<p>COMPLETE RevitaLens Multi-Purpose Disinfecting Solution</p> <p>ACUVUE RevitaLens Multi-Purpose Disinfecting Solution</p> <p>Formulation 9608X</p>	<p>Class IIb Rule 15</p>
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We, AMO Ireland declare exclusively under sole responsibility that the device(s) listed above meet the provisions of Annex II of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Standards Applied:

Applied standards are listed in the Essential Requirements Checklist RTF9608X-5040

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany

Notified Body Identification Number CE0123

EC Certificate Number: G1 18 06 01630 009

Start of CE Marking 2018-07-16

Signature of Regulatory Representative:

Name and Title:

Carsten Rupprath, Director Regulatory Affairs, EMEA

Ettlingen, Germany

Carsten Rupprath

Digitally signed by Carsten Rupprath
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Date: 2021.03.22 16:13:13 +01'00'
Adobe Reader version: 11.0.10

Signature

Date

Signature of Quality Representative:

Name and Title:

Vincent Jordan, Director Business and Regional Quality Assurance EMEA for Johnson & Johnson Vision

Dublin, Ireland

Vincent Jordan

Digitally signed by Vincent Jordan
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Date

Based on the Declaration of Conformity for Johnson & Johnson Surgical Vision, Inc. (PH3050).