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

Devices Concerned

Catalog Number/Model Number	Product Name	Device Classification
Applicable SKU: Complete RevitaLens 93686NRH, 93686UFH, 93686RHH, 93686KZH, 93686SAH, 93751EQH, 93751RWH, 93752RYH, 93752RRH, 93744AXH, 93744FLH, 93744GMH, 93744EJH, 93744RWH, 93744RYH, 93745AXH, 93745GMH, 93822GMH, 93823GMH, 93756GMH, 93755RRH, 94012RH, and 94012FL ACUVUE RevitaLens: 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 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.	COMPLETE RevitaLens Multi-Purpose Disinfecting Solution ACUVUE RevitaLens Multi-Purpose Disinfecting Solution Formulation 9608X	Class IIb Rule 15

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
DN: c=US, o=JNJ, ou=Subscribers, cn=Carsten Rupprath, 0.9.2342.19200300.100.1.1=155003728
Reason: I attest to the accuracy and integrity of this document.
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
DN: c=US, o=JNJ, ou=Subscribers, cn=Vincent Jordan, 0.9.2342.19200300.100.1.1=152070173
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Date: 2021.03.12 17:04:56 Z
Adobe Reader version: 11.0.10

Signature Date

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