DECLARATION OF CONFORMITY

Manufacturer:
AMO Ireland
Block B
Liffey Valley Office Campus
Quarryvale,
Co. Dublin,
IRELAND
SRN: IE-MF-000013704

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	Formulation 9608X Product Names	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	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 001630 0011
Start of CE Marking certificate:	2021-03-12

Note: This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes.

We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.

Signature of Regulatory Representative:

Name and Title:

Nicole Kassner, Associate Director Regulatory Affairs, Johnson & Johnson Vision

Nicole Kassner

Digitally signed by Nicole Kassner
DN: c=US, o=JNJ, ou=Subscribers, cn=Nicole Kassner, 0.9.2342.19200300.100.1.1=1061116
Reason: I attest to the accuracy and integrity of this document.
Date: 2021.11.06 15:33:35 -04'00'
Adobe Acrobat version: 11.0.20

Signature Date

Signature of Quality Representative:

Name and Title:

Vincent Jordan, CQ Director EMEA for Johnson & Johnson Vision, Dublin, Ireland

Vincent Jordan

Digitally signed by Vincent Jordan
DN: cn=Vincent Jordan, o=JNJ, ou=152070173, email=vjordan2@its.jnj.com, c=IE
Reason: I attest to the accuracy and integrity of this document.
Date: 2021.11.16 17:27:13 Z
Adobe Reader version: 11.0.23

Signature Date