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 7167X Product Name**	**Device Classification**
Applicable SKU: 93043EW, 93044AX, 93047GB, 93047RH, 93050AX, 93051FP, 93053EJ, 93053GB, 93053RH, 93057FM, 93106RH, 93106TC, 93366EW, 93783GM. 93784GM, 94376GA, 94378AX	OxySept 1 Step Disinfecting Solution Oxysept Comfort	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 RTF7167-5020

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Müchen Germany
Notified Body Identification Number	CE0123
EC Certificate Number:	G1 001630 0011
Start of CE Marking Certificate (Date, Lot, or serial number):	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 agree to the terms defined by the placement of my signature on this document.
Date: 2021.11.05 11:13:10 -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 17:05:31 Z
Adobe Reader version: 11.0.23

Signature Date