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 8772X Product Names**	**Device Classification**
Applicable SKU: 90275XVH 94187CQ, 94187GM, 94187FL, 94187RR 94199RR 94200GM 90098AXH, 90098FLH, 90098GMH, 90098UQH, 90098QFH	 TotalCare 1 Blink TotalCare Daily Cleaner Blink TotalCare Starter Kit Blink TotalCare Twin Pack Blink-N-Clean	 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 RTF8772X-5020

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 (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 11:18:15 -04'00'
Adobe Acrobat version: 11.0.20

Signature Date

Signature of Quality Representative:

Name and Title:

Vincent Jordan, CQ Director EMEA, 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 17:10:13 Z
Adobe Reader version: 11.0.23

Signature Date