DECLARATION OF CONFORMITY

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

Manufacturer Production Facility:
Holopack Verpackungstechnik GmbH
Plant 1
Bahnhofstraße 18
74429 Sulzbach-Laufen
Germany

Holopack Verpackungstechnik GmbH
Plant 2
Bahnhofstraße 20
73453 Abtsgmünd-Untergröningen
Germany

Devices Concerned		
Catalog Number/Model Number	**9589X Product Family Names**	**Device Classification**
Applicable SKU: 93578AXH, 93578FLH, 93578GMH, 93578QFH, 94220QE, 94091NR, 93578LT, 93578SHH, 93578PR, 93578HE, 94091RN	Blink Intensive Soothing Eye Drops (Unit Dose) Blink Intensive Tears (Unit Dose) Blink Intensive Tears Protective Eye Drops (Unit Dose)	Class IIb Rule 5

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 RTF9589X-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 (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: 2021.11.06 15:51:16 -04'00'
Adobe Acrobat version: 11.0.20

Signature Date

Signature of Quality Representative:

Name and Title:

Vincent Jordan, Commercial Quality 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 17:27:58 Z
Adobe Reader version: 11.0.23

Signature Date