Johnson Johnson vision

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	9589X Product Family Names	Device
Number		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

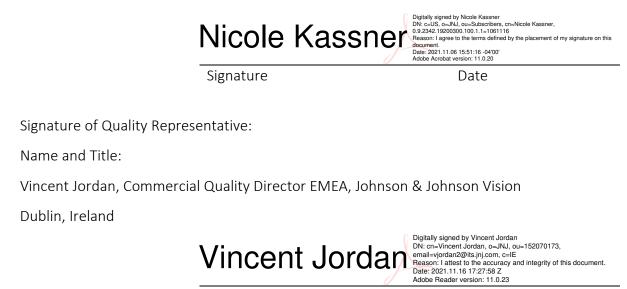
Note: This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes.

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



Signature

Date