

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 9464X Product Name	Device Classification
Applicable SKU:	Blink® Contacts Soothing Eye Drops	Class IIb Rule 5
90222AXAH, 90222FLH, 90222GMH, 90222QFH, 90222RWH, 90222SHH, 90222PR,	Blink® Refreshing Daily Eye Drops	
90222LT, 93903AXH		

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 RTF9464X-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 2021-03-12

(Date, Lot, or serial number):

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



Digitally signed by Nicole Kassner
DN: c=US, o=JNJ, ou=Subscribers, cn=Nicole Kassner.

Signature Date

Signature of Quality Representative:

Name and Title:

Vincent Jordan, CQ Director EMEA for Johnson & Johnson Vision

Dublin, Ireland



Adobe Reader version: 11.0.23

Signature

Date