

DECLARATION OF CONFORMITY

Manufacturer:

AMO Ireland Block B Liffey Valley Office Campus Quarryvale, D22 XOY3 Co. Dublin Ireland

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	Product Name	Device Classification
Applicable SKU:	Blink® Contacts Soothing Eye Drops	Class IIb Rule 15
90222AXAH, 90222FLH, 90222GMH, 90222QFH, 90222RWH, 90222SHH, 90222PR, 90222LT	Blink® Refreshing Daily Eye Drops	
93903AXH	Formulation 9464X	

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

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Notified Body: TÜV SÜD Product Service GmbH

Ridlerstraße 65 80339 München Germany

Notified Body Identification Number: CE0123

> G1 18 06 01630 009 EC Certificate Number:

Start of CE Marking 2018-07-16

(Date, Lot, or serial number):

Signature of Regulatory Representative:

Name and Title:

Carsten Rupprath, Director Regulatory Affairs, EMEA

Ettlingen, Germany



Digitally signed by Carsten Rupprath
DN: c=US, o=JNJ, ou=Subscribers, cn=Carsten Rupprath,

Signature

Date

Signature of Quality Representative:

Name and Title:

Vincent Jordan, Director Business and Regional Quality Assurance EMEA, Johnson & Johnson Vision

Dublin, Ireland

Vincent Jordan Digitally signed by Vincent Jordan Digitally Signed Digi

Signature

Date

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