

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® Intensive PLUS Liquid Gel Eye Drops	Class IIb Rule 5
93914AX, 93914QF, 93914GM, 93914FL, 93915AX, 93915GM, 93914PR, 93914SH	Formulation 9588X	

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 RTF9588X-5020

Notified Body: TÜV SÜD Product Service GmbH

Ridlerstraße 65 80339 München Germany

Notified Body Identification Number: CE0123

EC Certificate Number: G1180601630009

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
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