Johnson Johnson vision

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: 93577FL, 93577GB, 93577GM, 93577QF, 93577RW, 93577SHH, 93785GM, 93577GBP5, 93577LT, 93577PR	Blink [®] Intensive Blink [®] Intensive Tears Formulation 9587X	Class IIb Rule 15	

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 RTF9587X-5020

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany
Notified Body Identification Number	CE0123
EC Certificate Number:	G1 18 06 01630 009
Start of CE Marking	2018-07-16

PH 3053 REV. 3

Signature of Regulatory Representative:

Name and Title:

Carsten Rupprath, Director Regulatory Affairs, EMEA

Ettlingen, Germany



Signature

Date

Signature of Quality Representative:

Name and Title:

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

Dublin, Ireland



Adobe Reader version: 11.0.10

Signature

Date