



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

<i>Devices Concerned</i>		
Catalog Number/Model Number	Product Name	Device Classification
Applicable SKU: 90275XVH	TotalCare 1	Class IIb Rule 15
94187CQ, 94187GM, 94187FL, 94187RR	Blink TotalCare Daily Cleaner	
94199RR 94200GM	Blink TotalCare Starter Kit Blink TotalCare Twin Pack	
90098AXH, 90098FLH, 90098GMH, 90098UQH, 90098QFH	Blink-N-Clean	
	Formulation 8772X	

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 RTF8772X-5020

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Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65 80339
München Germany

Notified Body Identification Number: CE0123

EC Certificate Number: G1 18 06 0160 009

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

Signature

Date

Signature of Quality Representative:

Name and Title:

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

Signature

Date

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