



CooperVision™

## Declaration of Conformity

CooperVision Manufacturing Ltd, South Point, Hamble, Southampton, SO31 4RF, United Kingdom, registered in England under Company no. 2737396, whose registered office address is Delta Park, Concorde Way, Segensworth North, Fareham, PO15 5RL, United Kingdom, declares that all device families listed below, which are detailed on the attached schedule, conform to The Essential Requirements as laid down in Annex I of the European Medical Devices Directive 93/42/EEC as amended by 2007/47/EC.

The Quality System employed by CooperVision Manufacturing Limited also complies with the provisions of Annex II of the European Medical Devices Directive 93/42/EEC.

CooperVision Manufacturing Limited declare conformity to Annexes II and V laid down in the European Medical Devices Directive, 93/42/EEC as amended by 2007/47/EC.

This declaration is supported by Approval of Conformity Certificate G1 103773 0002 Rev. 00 issued by TÜV SÜD Product Service GmbH who have been contracted as the Notified Body (identification number 0123) of CooperVision Manufacturing Limited and who have assessed the CooperVision Manufacturing Limited Quality Systems and compliance with the requirements of the European Medical Devices Directive 93/42/EEC. EC certificate G1 103773 0002 Rev. 00 is valid until 31<sup>st</sup> May 2021.

CooperVision Manufacturing Limited is exclusively responsible for this Declaration of Conformity.

### Soft (hydrophilic) contact lens products for the correction of ametropia:

- Comfilcon A soft contact lens products for (continuous) extended wear
- Enfilcon A soft contact lens products for daily wear
- Fanfilcon A soft contact lens products for daily wear
- Methafilcon A soft contact lens products for extended wear
- Methafilcon B soft contact lens products for extended wear
- Ocufilecon B soft contact lens products for daily disposable wear
- Ocufilecon D soft contact lens products for daily disposable wear
- Ocufilecon D soft contact lens products for extended wear
- Omafilecon A soft contact lens products for daily disposable wear
- Omafilecon A soft contact lens products for daily wear
- Omafilecon B soft contact lens products for daily wear
- Polymacon soft contact lens products for daily wear
- Polymacon soft contact lens products for extended wear
- Riofilecon A soft contact lens products for daily disposable wear
- Somofilcon A soft contact lens products for daily disposable wear
- Somofilcon A soft contact lens products for daily wear
- Stenfilcon A soft contact lens products for daily disposable wear
- Surfilcon A soft contact lens products for daily wear
- Tetrafilecon A soft contact lens products for extended wear
- Filcon IV1 + AquaTract soft contact lens products for daily disposable wear
- Methafilcon IV1 soft contact lens products for daily disposable wear

### Soft (hydrophilic) contact lens products for control of myopia:

- Omafilecon A soft contact lens products for daily disposable wear
- Somofilcon A soft contact lens products for daily disposable wear

### Soft contact lens care products:

- Multipurpose soft contact lens care solutions

### Rigid gas permeable contact lens care products:

- Multipurpose rigid gas permeable contact lens care solutions

### Ancillary products:

- Comfort drops
- Preservative free saline
- Nasal drops
- Eye moisturising drops
- Eye brightening drops
- Eye wash

Signed : E. Nelson

Date : 06.05.2020

RA Director, Europe, Africa & Central Eurasia  
CooperVision Manufacturing Limited  
Delta Park, Segensworth North, Fareham,  
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