



CooperVision™

Declaration of Conformity

CooperVision Manufacturing Ltd (also trading as **Aspect Vision Holdings Ltd, CooperVision, CooperVision Ltd, Hydron and Sauflon Pharmaceuticals Ltd**) of 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 Directive 93/42/EEC relating to Medical Devices, as implemented by the UK Medical Devices (Amendment) Regulations 2008 (SI 2008 No. 2936).

The Quality System employed by CooperVision Manufacturing Limited also complies with the provisions of Annex II of the European Directive 93/42/EEC relating to Medical Devices, as implemented by the UK Medical Devices (Amendment) Regulations 2008 (SI 2008 No. 2936).

This declaration is supported by Approval of Conformity Certificate 4002649/C issued by Lloyds Register Quality Assurance Limited who have been contracted as our Notified Body (number 0088) and who have assessed the CooperVision Manufacturing Limited Quality Systems and compliance with the requirements of the European Directive 93/42/EEC relating to Medical Devices, as implemented by the UK Medical Devices (Amendment) Regulations 2008 (SI 2008 No. 2936).

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
- Lidofilcon 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
- 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

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

Rigid Gas Permeable (RGP) contact lens products for the correction of ametropia:

- Rigid Gas Permeable (RGP) contact lens products for daily wear

Soft contact lens care products:

- Multipurpose soft contact lens care solutions

Signed: 
Director of QA & Regulatory Affairs

Date: 2 APRIL 2015

**SCHEDULE OF DEVICES TO WHICH CE MARKING IS TO BE AFFIXED**

CE 0088 marking is to be affixed to the following devices, and all CE Marked branded variants, which are designed and manufactured by CooperVision Manufacturing Limited.

All contact lens products listed are Class IIa Medical Devices (Rule 5, Annex IX, Directive 93/42/EEC).

All contact lens care products listed are Class IIb Medical Devices (Rule 15, Annex IX, Directive 93/42/EEC).

Soft Contact Lens Products for the Correction of Ametropia**Comfilcon A soft contact lens products for continuous wear**

Biofinity / Biofinity XR	Biofinity Toric
Biofinity Multifocal	

Enfilcon A soft contact lens products for daily wear

Avaira	Avaira Toric
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Lidofilcon A soft contact lens products for daily wear

Omniflex	Omniflex Toric
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Methafilcon A soft contact lens products for extended wear

Crazy Lenses	Frequency 55 Aspheric
Expressions Accents	Frequency 55 Multifocal
Expressions Colors	Frequency 58 UV
Formula 55 UV	Frequency XCEL Toric / Toric XR
Frequency 55	Images

Methafilcon B soft contact lens products for extended wear

CV 55	Hydrasoft XW
Frequency 55 Toric	Hydrasoft Toric
Hydrasoft	Hydrasoft Toric XW

Ocufilecon B soft contact lens products for daily disposable wear

Biomedics 1 Day



Ocufilcon D soft contact lens products for daily disposable wear

Biomedics 1 Day Extra

Biomedics 1 Day Toric

Ocufilcon D soft contact lens products for extended wear

Asphere 55 UV

Edge III UV

Biomedics 55

Edge III Biomedics 55 UV

Edge III 55

Toric 55 UV

Omafilcon A soft contact lens products for daily disposable wear

Proclear 1 Day

Proclear 1 Day Multifocal

Omafilcon A soft contact lens products for daily wear

Proclear

Proclear XC

Proclear Tailor-Made-Toric

Omafilcon B soft contact lens products for daily wear

Proclear Sphere

Proclear Multifocal Toric

Proclear Multifocal

Proclear Toric

Polymacon soft contact lens products for daily wear

Frequency 38

ST-Kontur 38 Toric

Silver 07

Zero 6

ST-Kontur 38

Zero 6 Toric

Polymacon soft contact lens products for extended wear

Edge III 38

Edge III Thin 38

Edge III Biomedics 38

Edge III Versa-Scribe 38

Edge III Standard 38

Edge III XT 38



Somofilcon A soft contact lens products for daily disposable wear	
Clariti 1 Day	Clariti 1 Day Multifocal Toric
Clariti 1 Day Toric	Select 1 Day
Clariti 1 Day Multifocal	

Somofilcon A soft contact lens products for daily wear	
Clariti	Clariti Multifocal Toric
Clariti Toric	Clariti Multifocal Toric XR
Clariti XR Toric	Clariti Elite
Clariti Multifocal	Select

Stenfilcon A soft contact lens products for daily disposable wear	
MyDay	

Surfilcon A soft contact lens products for daily wear	
Lunelle Spherique	Lunelle Variations
Lunelle Torique	Rhythmic UV
Lunelle Torique Rx	Rhythmic UV Multifocal

Tetrafilcon A soft contact lens products for extended wear	
Cooper HT	Preference Standard
Cooper Toric	Vantage
CooperClear	Vantage Accents
Preference Toric	Vantage Thin
CV 43	Vantage Thin Accents
Preference	

Soft Contact Lens Products for the Control of Myopia

Omafilcon A soft contact lens products for daily disposable wear	
MiSight	

Somofilcon A soft contact lens products for daily disposable wear	
Clariti 1 Day Myopia Multifocal	



RGP Contact Lens Products for the Correction of Ametropia

RGP contact lens products for daily wear	
Lenticon RGP	Cornélia RGP

Soft Contact Lens Care Products

Multipurpose soft contact lens care solutions	
Options Multi	Biomedics All-In-One

Authorised By: 
Director of QA & Regulatory Affairs

Date: 2 APRIL 2015