

## **Part 1: Declaration of Conformity Statement**

**CooperVision Manufacturing Limited**, 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 base products that constitute each of the generic device groups as listed below in part 2, also including those products listed under the device sub-category: Ancillary products, conform to the Essential Requirements as laid down in Annex I of the European Medical Devices Directive 93/42/EEC, as amended.

Devices are commercialised under the trade name 'CooperVision'.

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 declares conformity to Annex II laid down in the European Medical Devices Directive 93/42/EEC, as amended.

This declaration is supported by EC Certificate G1 103773 0005 Rev. 01 issued by TÜV SÜD Product Service GmbH with address Ridlerstraße 65, 80339 München, Germany, 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 0005 Rev. 01 is valid until 26<sup>th</sup> May 2024.

CooperVision Manufacturing Limited is the manufacturer of all listed devices and is exclusively responsible for this Declaration of Conformity.

References to all applied standards (including harmonised standards) can be found in QMS documents CHT02966, CHT02967, CHT02968 as applicable.

European Representative: CooperVision CL Kft. With address: Gorcsev Ivan Street 7. Building C. 2360 Gyal, Hungary.

### **Device sub-category: Soft (hydrophilic) contact lens products for the correction of ametropia:**

- **Generic device group:** comfilcon A soft contact lens products for (continuous) extended wear
- **Generic device group:** fanfilcon A soft contact lens products for daily wear
- **Generic device group:** methafilcon A soft contact lens products for extended wear
- **Generic device group:** ocufilcon B soft contact lens products for daily disposable wear
- **Generic device group:** ocufilcon D soft contact lens products for daily disposable wear
- **Generic device group:** ocufilcon D soft contact lens products for extended wear
- **Generic device group:** omafilcon A soft contact lens products for daily disposable wear
- **Generic device group:** omafilcon B soft contact lens products for daily wear
- **Generic device group:** riofilcon A soft contact lens products for daily disposable wear
- **Generic device group:** somofilcon A soft contact lens products for daily disposable wear
- **Generic device group:** somofilcon A soft contact lens products for daily wear
- **Generic device group:** stenfilcon A soft contact lens products for daily disposable wear

### **Device sub-category: Soft (hydrophilic) contact lens products for control of myopia:**

- **Generic device group:** omafilcon A soft contact lens products for daily disposable wear

### **Device sub-category: Soft contact lens care products:**

- **Generic device group:** Multipurpose soft contact lens care solutions

### **Device sub-category: Rigid gas permeable contact lens care products:**

- **Generic device group:** Multipurpose rigid gas permeable contact lens care solutions

### **Device sub-category: Ancillary products:**

- Comfort drops
- Preservative free saline

## Part 2: Product Schedule (base products and corresponding product codes)

CE 0123 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).

Ancillary products listed are class IIb medical devices Rule 15, Annex IX, Directive 93/42/EEC).

### Device sub-category: Soft Contact Lens Products for the Correction of Ametropia

Generic Device Group: comfilcon A soft contact lens products for continuous wear			
Base Product	Product Code	Base Product	Product Code
Biofinity / Biofinity XR	LENS051	Biofinity Toric	LENS042
Biofinity Multifocal	LENS117	Biofinity XR Toric	LENS215
Biofinity Energys	LENS203	Biofinity toric multifocal	LENS223

Generic Device Group: fanfilcon A soft contact lens products for daily wear			
Base Product	Product Code	Base Product	Product Code
Avaira vitality	LENS200	Avaira vitality Toric	LENS201

Generic Device Group: methafilcon A soft contact lens products for extended wear			
Base Product	Product Code	Base Product	Product Code
Frequency 55 Aspheric	LENS006	Frequency XCEL Toric	LENS012

Generic Device Group: ocufilcon B soft contact lens products for daily disposable wear	
Base Product	Product Code
Biomedics 1 Day	LENS056

Generic Device Group: ocufilcon D soft contact lens products for daily disposable wear			
Base Product	Product Code	Base Product	Product Code
Biomedics 1 day extra	LENS162	Biomedics 1 day extra toric	LENS014

Generic Device Group: ocufilcon D soft contact lens products for extended wear			
Base Product	Product Code	Base Product	Product Code
Biomedics 55 evolution asphere	LENS002	Biomedics Toric	LENS057
Biomedics now	LENS251		

Generic Device Group: omafilcon A soft contact lens products for daily disposable wear			
Base Product	Product Code	Base Product	Product Code
Proclear 1 Day	LENS026	Proclear 1 Day Multifocal	LENS169

<b>Generic Device Group: omafilcon B soft contact lens products for daily wear</b>			
<b>Base Product</b>	<b>Product Code</b>	<b>Base Product</b>	<b>Product Code</b>
Proclear Sphere	LENS008	Proclear Multifocal Toric	LENS086
Proclear Multifocal	LENS040	Proclear Toric	LENS015
Proclear multifocal XR	LENS144	Proclear toric XR	LENS087

<b>Generic Device Group: riofilcon A soft contact lens products for daily disposable wear</b>	
<b>Base Product</b>	<b>Product Code</b>
riofilcon A One Day	LENS238

<b>Generic Device Group: somofilcon A soft contact lens products for daily disposable wear</b>			
<b>Base Product</b>	<b>Product Code</b>	<b>Base Product</b>	<b>Product Code</b>
Clariti 1 Day	LENS206	Clariti 1 Day Multifocal	LENS208
Clariti 1 Day Toric	LENS244	Select 1 Day	LENS240

<b>Generic Device Group: somofilcon A soft contact lens products for daily wear</b>			
<b>Base Product</b>	<b>Product Code</b>	<b>Base Product</b>	<b>Product Code</b>
Clariti Elite	LENS212	Clariti Multifocal Toric	LENS218
Clariti Toric	LENS213	Clariti Multifocal Toric XR	LENS219
Clariti XR Toric	LENS220	Clariti Multifocal	LENS214

<b>Generic Device Group: stenfilcon A soft contact lens products for daily disposable wear</b>			
<b>Base Product</b>	<b>Product Code</b>	<b>Base Product</b>	<b>Product Code</b>
MyDay	LENS176	MyDay Toric	LENS232
MyDay Multifocal	LENS241	MyDay Energys	LENS239

**Device sub-category: Soft Contact Lens Products for the Control of Myopia**

<b>Generic Device Group: omafilcon A soft contact lens products for daily disposable wear</b>	
<b>Base Product</b>	<b>Product Code</b>
MiSight	LENS143

**Device sub-category: Soft Contact Lens Care Products**

<b>Generic Device Group: Multipurpose soft contact lens care solutions</b>			
<b>Base Product</b>	<b>Product Code</b>	<b>Base Product</b>	<b>Product Code</b>
HyCare	CLC005	All In One Light	CLC001
Refine One Step	CLC003	Comfortvue	CLC013
Cycleclean	CLC004		

**Device sub-category: Rigid Gas Permeable Contact Lens Care Products**

<b>Generic Device Group: Multipurpose rigid gas permeable contact lens care solutions</b>			
<b>Base Product</b>	<b>Product Code</b>	<b>Base Product</b>	<b>Product Code</b>
Delta Cleaner	CLC012	Delta DSW	CLC011

**Device sub-category: Ancillary Products**

Ancillary Products			
Base Product	Product Code	Base Product	Product Code
Comfort drops	CLC009	Preservative free saline	CLC014



Signed: \_\_\_\_\_

Date: 10<sup>th</sup> May 2021

Chris Dawson  
Senior Regulatory Affairs Specialist  
CooperVision Manufacturing Limited  
Delta Park, Segensworth North, Fareham  
United Kingdom, PO15 5RL