

## **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**

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

| <b>Generic Device Group: fanfilcon 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> |
| Avaira vitality  | LENS200             | Avaira vitality Toric | LENS201             |

| <b>Generic Device Group: methafilcon A soft contact lens products for extended wear</b> |                     |                      |                     |
|---|---------------------|----------------------|---------------------|
| <b>Base Product</b>   | <b>Product Code</b> | <b>Base Product</b>  | <b>Product Code</b> |
| Frequency 55 Aspheric   | LENS006             | Frequency XCEL Toric | LENS012             |

| <b>Generic Device Group: oculifilcon B soft contact lens products for daily disposable wear</b> |                     |
|---|---------------------|
| <b>Base Product</b>   | <b>Product Code</b> |
| Biomedics 1 Day   | LENS056             |

| <b>Generic Device Group: oculifilcon D 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> |
| Biomedics 1 day extra   | LENS162             | Biomedics 1 day extra toric | LENS014             |

| <b>Generic Device Group: oculifilcon D soft contact lens products for extended wear</b> |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| <b>Base Product</b>   | <b>Product Code</b> | <b>Base Product</b> | <b>Product Code</b> |
| Biomedics 55 evolution asphere  | LENS002             | Biomedics Toric     | LENS057             |
| Biomedics now   | LENS251             |                     |                     |

| <b>Generic Device Group: omafilcon 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> |
| 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              |



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**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

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