Manufacturer's Declaration in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificate G1 103773 0005 Rev 1. issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificate) *and*
- the compliance of the devices listed in the 'Schedule of Devices' section and CooperVision Manufacturing Limited, as the manufacturer of those devices, with the conditions necessary for the continued placing on the market and putting into service.

Manufacturer name	CooperVision Manufacturing Limited
Manufacturer address	South Point, Hamble, Southampton, SO31 4RF, United Kingdom
Single Registration Number (SRN)	GB-MF-000021104

Authorised Representative name	CooperVision CL Kft.
Authorised Representative address	Gorcsev Iván street 7. Building C. 2360 Gyál, Hungary
Single Registration Number (SRN)	HU-AR-000020102

Notified body name	TÜV SÜD Product Service GmbH
Notified body number	0123
Directive Certificate number to which this confirmation is made	G1 103773 0005 Rev 1.
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26 May 2024
End date of extended validity/transition period	31 December 2028

We, CooperVision Manufacturing Limited, as the manufacturer declare under our sole responsibility that:

- for the above listed **Directive Certificate,** the conditions for the legal extension of validity as required in Article 120.2 of the MDR have been met *and*
- the listed **devices** in the attached schedule and CooperVision Manufacturing Limited as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate** as listed above
  - Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not since been withdrawn.
  - Expires after 20 March 2023:
    - Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment was submitted by CooperVision Manufacturing Limited to a notified body before 26 May 2024 for the devices listed in the attached schedule or their substitutes and signed written agreement will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Quality Management System (QMS)**
  - A QMS in accordance with Article 10(9) MDR is in place.

- **Devices as listed in the attached schedule**
  - The devices continue to comply with the requirements of the Medical Devices Directive, 93/42/EEC (MDD).
  - There are no significant changes in the design or intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer by the person responsible for regulatory compliance (PRRC):

Manufacturer Name	CooperVision Manufacturing Limited
Location	South Point, Hamble, Southampton, SO31 4RF, United Kingdom
Print Name, Title	Clive Rendle, Quality Assurance/Regulatory Compliance Director
Signature & Date	DocuSigned by: Clive Rendle 22 April 2024 074C756228C1400...
Print Name, Title	Louisa Ballard, Senior Director, Regulatory Affairs EMEA
Signature & Date	DocuSigned by: Louisa Ballard 22 April 2024 E8F33DC0ADC3452...
Print Name, Title	Ed Tavner, Senior Director, Global Regulatory Affair
Signature & Date	DocuSigned by: Ed Tavner 22 April 2024 43504A47D81642D...

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the devices (General medical device name and LENS no.)		**Substitute Devices** (if applicable)	
Soft (Hydrophilic) Contact Lens Products for the Correction of Ametropia			
riofilcon A sphere Daily Disposal Contact Lenses	LENS238	riofilcon A asphere Daily Disposal Contact Lenses	LENS260
somofilcon A sphere Daily Disposal Contact Lenses	LENS206	somofilcon A sphere Daily Disposal Contact Lenses	LENS247
somofilcon A multifocal Daily Disposal Contact Lenses	LENS208	somofilcon A multifocal Daily Disposal Contact Lenses	LENS253
comfilcon A sphere Frequent Replacement Contact Lenses	LENS051	N/A	N/A
comfilcon A sphere XR Frequent Replacement Contact Lenses	LENS051	N/A	N/A
comfilcon A toric Frequent Replacement Contact Lenses	LENS042	N/A	N/A
comfilcon A XR toric Frequent Replacement Contact Lenses	LENS215	N/A	N/A
comfilcon A multifocal Frequent Replacement Contact Lenses	LENS117	N/A	N/A
comfilcon A toric multifocal Frequent Replacement Contact Lenses	LENS223	N/A	N/A
comfilcon A asphere Frequent Replacement Contact Lenses	LENS203	N/A	N/A
fanfilcon A sphere Frequent Replacement Contact Lenses	LENS200	N/A	N/A
fanfilcon A toric Frequent Replacement Contact Lenses	LENS201	N/A	N/A
omafilcon B toric XR Frequent Replacement Contact Lenses	LENS087	N/A	N/A
omafilcon B multifocal XR Frequent Replacement Contact Lenses	LENS144	N/A	N/A

Identification of the devices (General medical device name and LENS no.)		**Substitute Devices** (if applicable)	
Soft (Hydrophilic) Contact Lens Products for the Correction of Ametropia			
ocufilcon D sphere Daily Disposal Contact Lenses	LENS162	N/A	N/A
ocufilcon D toric Daily Disposal Contact Lenses	LENS014	N/A	N/A
ocufilcon D asphere Frequent Replacement Contact Lenses	LENS002	N/A	N/A
ocufilcon D toric Frequent Replacement Contact Lenses	LENS057	N/A	N/A
omafilcon A sphere Daily Disposal Contact Lenses	LENS026	N/A	N/A
omafilcon A multifocal Daily Disposal Contact Lenses	LENS169	N/A	N/A
omafilcon B sphere Frequent Replacement Contact Lenses	LENS008	N/A	N/A
omafilcon B toric Frequent Replacement Contact Lenses	LENS015	N/A	N/A
omafilcon B multifocal Frequent Replacement Contact Lenses	LENS040	N/A	N/A
omafilcon B multifocal toric Frequent Replacement Contact Lenses	LENS086	N/A	N/A
somofilcon A toric Daily Disposal Contact Lenses	LENS244	N/A	N/A
somofilcon A sphere Daily Disposal Contact Lenses	LENS240	N/A	N/A
stenfilcon A asphere Daily Disposal Contact Lenses Contact Lenses	LENS176	N/A	N/A
stenfilcon A toric Daily Disposal Contact Lenses	LENS232	N/A	N/A
stenfilcon A multifocal Daily Disposal Contact Lenses	LENS241	N/A	N/A
stenfilcon A asphere Daily Disposal Contact Lenses	LENS239	N/A	N/A

Identification of the devices (General medical device name and LENS no.)		**Substitute Devices** (if applicable)	
Soft (Hydrophilic) Contact Lens Products for the Control of Myopia			
omafilcon A Myopia Management Daily Disposal Contact Lenses	LENS143	N/A	N/A

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