

Declaration of Conformity

CooperVision Manufacturing Ltd (also trading as **Aspect Vision Care, Aspect Vision Care Ltd, Aspect Vision Holdings Ltd, CL Tinters, CooperVision, CooperVision Ltd, Hydron, Hydron Ltd, Ocular Sciences and Ocular Sciences Ltd**) declares that all device families listed below, which are detailed on the attached list (Issue 48 FM-WP-037), 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 Regulations 2002 (SI 2002 No 618).

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 Regulations 2002 (SI 2002 No 618).

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 Regulations 2002 (SI 2002 No 618).

Soft 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 A soft contact lens products for daily 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
- Polymacon soft contact lens products for daily wear
- Polymacon soft contact lens products for extended wear
- Surfilecon A soft contact lens products for daily wear
- Tetrafilecon A soft contact lens products for extended wear

Soft contact lens care products:

- Multipurpose soft contact lens care solutions

Signed: 
Martin Newman
Director of QA & Regulatory Affairs

Date: 5th February 2009

SCHEDULE OF DEVICES TO WHICH CE MARKING IS TO BE AFFIXED
ISSUE NO 48:

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
Comfilcon A soft contact lens products for continuous wear

Biofinity	Biofinity Toric
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Enfilcon A soft contact lens products for daily wear

Avaira

Lidofilcon A soft contact lens products for daily wear

Actifresh 400	Lunelle Variations
Lunelle Spherique	Omniflex
Lunelle Torique	Omniflex Toric
Lunelle Torique Rx	

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
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

SCHEDULE OF DEVICES TO WHICH CE MARKING IS TO BE AFFIXED
Ocufilcon A soft contact lens products for daily wear

Actitonic

Ultra T

Ocufilcon B soft contact lens products for daily disposable wear

Biomedics 52 1-Day

Ocufilcon D soft contact lens products for daily disposable wear

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

Ocufilcon A soft contact lens products for daily wear

Actitonic

Ultra T

Omafilcon A soft contact lens products for daily disposable wear

Proclear 1 Day

Omafilcon A soft contact lens products for daily wear

Proclear

Proclear Tailor-Made-Toric

Proclear Multifocal

Proclear Toric

Proclear Multifocal Toric

Proclear XC

Polymacon soft contact lens products for daily wear

Frequency 38

Silver 38 Thin

Prosthetic

Zero 6

Silver 07

Zero 6 Toric

Silver 2

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

Surfilcon A soft contact lens products for daily wear

Rhythmic UV	Rhythmic UV Multifocal
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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 Care Products**Multipurpose soft contact lens care solutions**

Options Multi	Biomedics All-In-One
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Authorised By:


QA & Regulatory Affairs Director
Date: 5th February 2009