

EC Declaration of Conformity

Manufacturers Name: Euro Optics BV

Manufacturers Address: Petunialaan 11A
5582 Aalst Waalre
The Netherlands

SRN (Single Registration Number): NL-MF-000033415

**Authorized Representative Name
And Address (if applicable):** Not applicable

Basic UDI-DI/ GMN: Ready Made Eyewear, Full Rim, Plastic - 8713228REFRP33
Ready Made Eyewear, Full Rim, Metal - 8713228REFRM2V
Ready Made Eyewear, Full Rim, Mix - 8713228REFRMIX5P
Ophthalmic Frames, Full Rim, Metal - 8713228OFFRM23
Ophthalmic Frames, Full Rim, CP - 8713228OFFRCPYS
Ophthalmic Frames, Full Rim, Mix - 8713228OFFRMIX4H

Name of the Device (s): Ready Made Eyewear (RE), Optical Frames (OF)

Product code: See Attachment 1

Risk Class: MDR class I, rule 1 according to Annex VIII of Regulation (EU) 2017/745

Notified Body name: Not applicable

Notified Body Identification number: Not applicable

**Conformity assessment route:
(Regulation (EU) 2017/745)** Annex II, III, IV

Applicable standards: ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for regulatory purposes
ISO 14971: 2019 – Medical Devices – Application of risk management to medical devices
EN 14139:2010 - Ophthalmic optics - specifications for ready to wear spectacles
ISO 16034:2002(E) - Ophthalmic optics - specifications for single-vision ready-to-wear near-vision spectacles
ISO 12870:2024 - Ophthalmic optics - Spectacle frames - Requirements and test methods.

This Declaration of Conformity is issued under the sole responsibility of Euro Optics BV.

We hereby declare that the medical device(s) as specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality Management System approval and compliance of the organization with ISO 13485:2016.

All supporting documentation is retained at the premises of the Legal Manufacturer.

Signature:


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Place and date of issue:

Waalre 2025.06.12

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Chapter 1.1.10 DoC v04	Date: 25-02-2025

Ready Made Eyewear, Full Rim, Plastic				
Basic UDI-DI: 8713228REFRP33				
GMDN: 43832				
EMDN: Q0210030102				
Intended Use: ready made eyewear, also known as reading glasses, are intended to be used to improve near vision & reading. The glasses are available in various magnification levels, typically ranging from +1.0 to +3.0 diopters, allowing users to comfortably read without a prescription.				
Item/Serial Number	GTIN	UDI-DI		Brand
MP2040	8595052608202	8713228REFRP33		Infocus
MP2068	8595052608011	8713228REFRP33		Infocus
MP2078	8595052608004	8713228REFRP33		Infocus
MP2081	8595052608233	8713228REFRP33		Infocus
MP2086	8595052608103	8713228REFRP33		Infocus
MP2087	8595052608059	8713228REFRP33		Infocus
MP2092	8595052608066	8713228REFRP33		Infocus
MP4000	8595052608226	8713228REFRP33		Infocus
MP4161	8595052608110	8713228REFRP33		Infocus
MP4169	8595052608127	8713228REFRP33		Infocus
MP4170	8595052608134	8713228REFRP33		Infocus
MP4181	8595052608028	8713228REFRP33		Infocus
MP6228	8595052608035	8713228REFRP33		Infocus
MP6230	8595052608141	8713228REFRP33		Infocus
MP6233	8595052608042	8713228REFRP33		Infocus
MP6234	8595052608158	8713228REFRP33		Infocus
MP6241	8595052608196	8713228REFRP33		Infocus
MP6242	8595052608073	8713228REFRP33		Infocus
MP6245	8595052608219	8713228REFRP33		Infocus
MP6246	8595052608080	8713228REFRP33		Infocus
MP6247	8595052608097	8713228REFRP33		Infocus
MP7401	8595052608165	8713228REFRP33		Infocus

Ready Made Eyewear, Full Rim, Metal				
Basic UDI-DI: 8713228REFRM2V				
GMDN: 43832				
EMDN: Q0210030101				
Intended Use: ready made eyewear, also known as reading glasses, are intended to be used to improve near vision & reading. The glasses are available in various magnification levels, typically ranging from +1.0 to +3.0 diopters, allowing users to comfortably read without a prescription.				
Item/Serial Number	GTIN	UDI-DI	Colours	Brand
MP1044	8595052608172	8713228REFRM2V		Infocus
MP1045	8595052608189	8713228REFRM2V		Infocus

Ready Made Eyewear, Full Rim, Mix				
Basic UDI-DI: 8713228REFRPMIX5P				
GMDN: 43832				
EMDN: Q0210030103				