

CE Declaration of Conformity

Manufacturers Name: Euro Optics BV

Manufacturers Address: Petunialaan 11
5582 HA 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

Classification: 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: Euro Optics BV uses the following procedures for the CE-labelling of their products according to the Regulation MDR 2017/745:
EC conformity declaration according to MDR, 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 - 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 01-01-2026

Technical File Euro Optics BV	Page 1 of 6
Chapter 1.1.10 DoC v03	Date: 03-07-2024

Attachment 1 – Types, models, UDI-DI

Ready Made Eyewear, Full Rim, Plastic				
Basic UDI-DI: 8713228REFRP33				
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		Brand
R2068	8713228858101	8713228REFRP33		Infocus
R2068-10	8713228858255	8713228REFRP33		Infocus
R2068-15	8713228858194	8713228REFRP33		Infocus
R2068-20	8713228858200	8713228REFRP33		Infocus
R2068-25	8713228858217	8713228REFRP33		Infocus
R2068-30	8713228858224	8713228REFRP33		Infocus
R2068-35	8713228858231	8713228REFRP33		Infocus
R2068-40	8713228858248	8713228REFRP33		Infocus
R2087	8713228872848	8713228REFRP33		Infocus
R2089	8713228872756	8713228REFRP33		Infocus
R2090	8713228872855	8713228REFRP33		Infocus
R2091	8713228872763	8713228REFRP33		Infocus
R2092	8713228872862	8713228REFRP33		Infocus
R2093	8713228875689	8713228REFRP33		Infocus
R2094	8713228875696	8713228REFRP33		Infocus
R2095	8713228875702	8713228REFRP33		Infocus
R2096	8713228875719	8713228REFRP33		Infocus
R2097	8713228875726	8713228REFRP33		Infocus
R4007	8713228825974	8713228REFRP33		Infocus
R4007-10	8713228846764	8713228REFRP33		Infocus
R4007-15	8713228846771	8713228REFRP33		Infocus
R4007-20	8713228846788	8713228REFRP33		Infocus
R4007-25	8713228846795	8713228REFRP33		Infocus
R4007-30	8713228846801	8713228REFRP33		Infocus
R4007-35	8713228846818	8713228REFRP33		Infocus
R4007-40	8713228846825	8713228REFRP33		Infocus
R4119	8713228855018	8713228REFRP33		Infocus
R4119-10	8713228855667	8713228REFRP33		Infocus
R4119-15	8713228855674	8713228REFRP33		Infocus
R4119-20	8713228855681	8713228REFRP33		Infocus
R4119-25	8713228855698	8713228REFRP33		Infocus
R4119-30	8713228855704	8713228REFRP33		Infocus
R4119-35	8713228855711	8713228REFRP33		Infocus
R4119-40	8713228855728	8713228REFRP33		Infocus
R4127	8713228855094	8713228REFRP33		Infocus
R4127-10	8713228855186	8713228REFRP33		Infocus
R4127-15	8713228855193	8713228REFRP33		Infocus
R4127-20	8713228855209	8713228REFRP33		Infocus
R4127-25	8713228855216	8713228REFRP33		Infocus
R4127-30	8713228855223	8713228REFRP33		Infocus
R4127-35	8713228855230	8713228REFRP33		Infocus
R4127-40	8713228855247	8713228REFRP33		Infocus
R4155	8713228858644	8713228REFRP33		Infocus
R4162	8713228860739	8713228REFRP33		Infocus

R4163	8713228860746	8713228REFRP33	Infocus
R4167	8713228860784	8713228REFRP33	Infocus
R4177	8713228860883	8713228REFRP33	Infocus
R4179	8713228864973	8713228REFRP33	Infocus
R4182	8713228865000	8713228REFRP33	Infocus
R4187	8713228865055	8713228REFRP33	Infocus
R4191	8713228872879	8713228REFRP33	Infocus
R4192	8713228872770	8713228REFRP33	Infocus
R4193	8713228872787	8713228REFRP33	Infocus
R4194	8713228872794	8713228REFRP33	Infocus
R4195	8713228872800	8713228REFRP33	Infocus
R4196	8713228872886	8713228REFRP33	Infocus
R4197	8713228875733	8713228REFRP33	Infocus
R4198	8713228875740	8713228REFRP33	Infocus
R4199	8713228875757	8713228REFRP33	Infocus
R4200	8713228875764	8713228REFRP33	Infocus
R4201	8713228875771	8713228REFRP33	Infocus
R4202	8713228875788	8713228REFRP33	Infocus
R4203	8713228875795	8713228REFRP33	Infocus
R4204	8713228875801	8713228REFRP33	Infocus
R4205	8713228875818	8713228REFRP33	Infocus
R4206	8713228875825	8713228REFRP33	Infocus
R4207	8713228875832	8713228REFRP33	Infocus
R4208	8713228875849	8713228REFRP33	Infocus
R4209	8713228875856	8713228REFRP33	Infocus
R4210	8713228875863	8713228REFRP33	Infocus
R4211	8713228875870	8713228REFRP33	Infocus
R4806	8713228841608	8713228REFRP33	Infocus
R4809	8713228858040	8713228REFRP33	Infocus
R6231	8713228860937	8713228REFRP33	Infocus
R6241	8713228872817	8713228REFRP33	Infocus
R6242	8713228872893	8713228REFRP33	Infocus
R6243	8713228872824	8713228REFRP33	Infocus
R6244	8713228872909	8713228REFRP33	Infocus
R6246	8713228872916	8713228REFRP33	Infocus
R6247	8713228872923	8713228REFRP33	Infocus
R6248	8713228875887	8713228REFRP33	Infocus
R6249	8713228875894	8713228REFRP33	Infocus
R6250	8713228875900	8713228REFRP33	Infocus
R6251	8713228875917	8713228REFRP33	Infocus
R6252	8713228875924	8713228REFRP33	Infocus
R6253	8713228875931	8713228REFRP33	Infocus
R6254	8713228875948	8713228REFRP33	Infocus
R6255	8713228875955	8713228REFRP33	Infocus
R6256	8713228875962	8713228REFRP33	Infocus
R6257	8713228875979	8713228REFRP33	Infocus
R6258	8713228875986	8713228REFRP33	Infocus
R6259	8713228875993	8713228REFRP33	Infocus
R6260	8713228876006	8713228REFRP33	Infocus
R6261	8713228876013	8713228REFRP33	Infocus
R6900	8713228850310	8713228REFRP33	Infocus
R7400	8713228858262	8713228REFRP33	Infocus
R7403	8713228876020	8713228REFRP33	Infocus
R7404	8713228876037	8713228REFRP33	Infocus
R7620	8713228855360	8713228REFRP33	Infocus
R7622	8713228855384	8713228REFRP33	Infocus
R7623	8713228857876	8713228REFRP33	Infocus
R8905	8713228858071	8713228REFRP33	Infocus

RR4000	8713228860951	8713228REFRP33		Refocus
RR4004	8713228860999	8713228REFRP33		Refocus
RR7000	8713228860548	8713228REFRP33		Refocus

Ready Made Eyewear, Full Rim, Mix

Basic UDI-DI: 8713228REFRPMIX5P

GMDN: 43832

EMDN: Q0210030103

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
R4179	8713228864973	8713228REFRPMIX5P		Infocus
R4190	8713228865086	8713228REFRPMIX5P		Infocus
R8903	8713228852260	8713228REFRPMIX5P		Infocus

Ready Made Eyewear, Full Rim, Metal

Basic UDI-DI: 8713228REFRM2V

GMDN: 32816

EMDN: Q02100202

Intended Use: ophthalmic frames are intended to be used together with ophthalmic lenses, which are prescribed by a medical specialist, to correct vision problems by eyeglasses.

Item/Serial Number	GTIN	UDI-DI	Colours	Brand
R1031	8713228841530	8713228REFRM2V		Infocus
R1031-10	8713228846627	8713228REFRM2V		Infocus
R1031-15	8713228846634	8713228REFRM2V		Infocus
R1031-20	8713228846641	8713228REFRM2V		Infocus
R1031-25	8713228846658	8713228REFRM2V		Infocus
R1031-30	8713228846665	8713228REFRM2V		Infocus
R1031-35	8713228846672	8713228REFRM2V		Infocus
R1031-40	8713228846689	8713228REFRM2V		Infocus
R1043	8713228864904	8713228REFRM2V		Infocus
R1041	8713228860630	8713228REFRM2V		Infocus
R1044	8713228872725	8713228REFRM2V		Infocus
R1045	8713228872732	8713228REFRM2V		Infocus

Ophthalmic Frames, Full Rim, Metal				
Basic UDI-DI: 8713228OFFRM23				
GMDN: 32816				
EMDN: Q02100201				
Intended Use: ophthalmic frames are intended to be used together with ophthalmic lenses, which are prescribed by a medical specialist, to correct vision problems by eyeglasses.				
Item/Serial Number	GTIN	UDI-DI		Brand
M1000	8713228868148	8713228OFFRM23		N/A
M1001	8713228868155	8713228OFFRM23		N/A
M1002	8713228868162	8713228OFFRM23		N/A
M1003	8713228868179	8713228OFFRM23		N/A
M1004	8713228868186	8713228OFFRM23		N/A
M1005	8713228868193	8713228OFFRM23		N/A
M1006	8713228868209	8713228OFFRM23		N/A
M1007	8713228868216	8713228OFFRM23		N/A

Ophthalmic Frames, Full Rim, CP				
Basic UDI-DI: 8713228OFFRCPYS				
GMDN: 32816				
EMDN: Q02100202				
Intended Use: ophthalmic frames are intended to be used together with ophthalmic lenses, which are prescribed by a medical specialist, to correct vision problems by eyeglasses.				
Item/Serial Number	GTIN	UDI-DI		Brand
M2000	8713228862740	8713228OFFRCPYS		N/A
M2001	8713228862757	8713228OFFRCPYS		N/A
M2002	8713228862764	8713228OFFRCPYS		N/A
M2003	8713228862771	8713228OFFRCPYS		N/A
M2004	8713228868049	8713228OFFRCPYS		N/A
M2005	8713228868056	8713228OFFRCPYS		N/A
M4000	8713228862788	8713228OFFRCPYS		N/A
M4001	8713228862795	8713228OFFRCPYS		N/A
M4002	8713228862801	8713228OFFRCPYS		N/A
M4003	8713228862818	8713228OFFRCPYS		N/A
M4004	8713228862825	8713228OFFRCPYS		N/A
M4005	8713228862832	8713228OFFRCPYS		N/A
M4006	8713228867882	8713228OFFRCPYS		N/A
M4007	8713228867899	8713228OFFRCPYS		N/A
M4008	8713228867905	8713228OFFRCPYS		N/A
M4009	8713228867912	8713228OFFRCPYS		N/A
M4010	8713228867929	8713228OFFRCPYS		N/A
M4011	8713228867936	8713228OFFRCPYS		N/A
M4012	8713228867943	8713228OFFRCPYS		N/A
M4013	8713228867950	8713228OFFRCPYS		N/A
M4014	8713228867967	8713228OFFRCPYS		N/A
M4015	8713228867974	8713228OFFRCPYS		N/A
M4016	8713228867981	8713228OFFRCPYS		N/A
M4017	8713228867998	8713228OFFRCPYS		N/A
M4018	8713228868001	8713228OFFRCPYS		N/A
M4019	8713228868018	8713228OFFRCPYS		N/A
M4020	8713228868025	8713228OFFRCPYS		N/A
M4021	8713228868032	8713228OFFRCPYS		N/A
M4022	8713228868100	8713228OFFRCPYS		N/A
M4023	8713228868117	8713228OFFRCPYS		N/A
M4024	8713228868124	8713228OFFRCPYS		N/A

M4025	8713228868131	8713228OFFRCPYS		N/A
M6000	8713228862849	8713228OFFRCPYS		N/A
M6001	8713228862856	8713228OFFRCPYS		N/A
M6002	8713228862863	8713228OFFRCPYS		N/A
M6003	8713228862870	8713228OFFRCPYS		N/A
M6004	8713228862887	8713228OFFRCPYS		N/A
M6005	8713228862894	8713228OFFRCPYS		N/A
M6006	8713228868063	8713228OFFRCPYS		N/A
M6007	8713228868070	8713228OFFRCPYS		N/A
M6008	8713228868087	8713228OFFRCPYS		N/A
M6009	8713228868094	8713228OFFRCPYS		N/A

Ophthalmic Frames, Full Rim, Mix

Basic UDI-DI: 8713228OFFRMIX4H

GMDN: 32816

EMDN: Q02100203

Intended Use: ophthalmic frames are intended to be used together with ophthalmic lenses, which are prescribed by a medical specialist, to correct vision problems by eyeglasses.

Item/Serial Number	GTIN	UDI-DI		Brand

This Declaration of Conformity consist of a product family of Ready-Made-Eyewear and Optical Frames, with 3 possible colours per device. For every batch, a product code and identifier (UDI) will be affixed, to assure traceability.