

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 - 8713228REFRPMIX5P 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
Notified Body name:	Not applicable
Notified Body Identification number:	Not applicable

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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 14791: 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.

The reading glasses InFocus and InZoom are ordinary glasses. They are factory ready and do not require a prescription from an eye doctor or an eye specialist to make them.

The reading glasses InFocus and InZoom are binocular glasses. They are factory produced with two optical lenses with equal diopters.

Signature:


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Freek Bas
Euro Optics BV

Place and date of issue:

Waalre 05-07-2024

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Attachment 1 – Types, models, UDI-DI

Ready Made Eyewear, Full Rim, Plastic				
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		Brand
R2040	8713228849970	8713228REFRP33		Infocus
R2059	8713228857487	8713228REFRP33		Infocus
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
R2076	8713228860647	8713228REFRP33		Infocus
R2077	8713228860654	8713228REFRP33		Infocus
R2078	8713228860661	8713228REFRP33		Infocus
R2080	8713228860685	8713228REFRP33		Infocus
R2082	8713228864911	8713228REFRP33		Infocus
R2083	8713228864928	8713228REFRP33		Infocus
R2084	8713228864935	8713228REFRP33		Infocus
R2085	8713228864942	8713228REFRP33		Infocus
R2086	8713228864959	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
R4101	8713228850365	8713228REFRP33		Infocus
R4118	8713228855001	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

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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
R4140	8713228858132	8713228REFRP33	Infocus
R4148	8713228858576	8713228REFRP33	Infocus
R4149	8713228858583	8713228REFRP33	Infocus
R4155	8713228858644	8713228REFRP33	Infocus
R4159	8713228860708	8713228REFRP33	Infocus
R4160	8713228860715	8713228REFRP33	Infocus
R4161	8713228860722	8713228REFRP33	Infocus
R4162	8713228860739	8713228REFRP33	Infocus
R4163	8713228860746	8713228REFRP33	Infocus
R4164	8713228860753	8713228REFRP33	Infocus
R4165	8713228860760	8713228REFRP33	Infocus
R4166	8713228860777	8713228REFRP33	Infocus
R4167	8713228860784	8713228REFRP33	Infocus
R4169	8713228860807	8713228REFRP33	Infocus
R4170	8713228860814	8713228REFRP33	Infocus
R4171	8713228860821	8713228REFRP33	Infocus
R4172	8713228860838	8713228REFRP33	Infocus
R4173	8713228860845	8713228REFRP33	Infocus
R4174	8713228860852	8713228REFRP33	Infocus
R4175	8713228860869	8713228REFRP33	Infocus
R4176	8713228860876	8713228REFRP33	Infocus
R4177	8713228860883	8713228REFRP33	Infocus
R4180	8713228864980	8713228REFRP33	Infocus
R4181	8713228864997	8713228REFRP33	Infocus
R4182	8713228865000	8713228REFRP33	Infocus
R4183	8713228865017	8713228REFRP33	Infocus
R4185	8713228865031	8713228REFRP33	Infocus
R4186	8713228865048	8713228REFRP33	Infocus
R4189	8713228865079	8713228REFRP33	Infocus
R4806	8713228841608	8713228REFRP33	Infocus
R4808	8713228855261	8713228REFRP33	Infocus
R4809	8713228858040	8713228REFRP33	Infocus
R6111	8713228852512	8713228REFRP33	Infocus

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R6120	8713228855339	8713228REFRP33	Infocus
R6219	8713228858699	8713228REFRP33	Infocus
R6226	8713228858767	8713228REFRP33	Infocus
R6227	8713228860890	8713228REFRP33	Infocus
R6228	8713228860906	8713228REFRP33	Infocus
R6229	8713228860913	8713228REFRP33	Infocus
R6231	8713228860937	8713228REFRP33	Infocus
R6233	8713228865093	8713228REFRP33	Infocus
R6234	8713228865109	8713228REFRP33	Infocus
R6235	8713228865116	8713228REFRP33	Infocus
R6236	8713228865123	8713228REFRP33	Infocus
R6237	8713228865130	8713228REFRP33	Infocus
R6238	8713228865147	8713228REFRP33	Infocus
R6239	8713228865154	8713228REFRP33	Infocus
R6240	8713228865161	8713228REFRP33	Infocus
R6800	8713228850303	8713228REFRP33	Infocus
R6900	8713228850310	8713228REFRP33	Infocus
R7400	8713228858262	8713228REFRP33	Infocus
R7401	8713228865178	8713228REFRP33	Infocus
R7402	8713228865185	8713228REFRP33	Infocus
R7600	8713228825790	8713228REFRP33	Infocus
R7613	8713228838127	8713228REFRP33	Infocus
R7620	8713228855360	8713228REFRP33	Infocus
R7622	8713228855384	8713228REFRP33	Infocus
R7623	8713228857876	8713228REFRP33	Infocus
R8905	8713228858071	8713228REFRP33	Infocus
RR4000	8713228860951	8713228REFRP33	Refocus
RR4001	8713228860968	8713228REFRP33	Refocus
RR4002	8713228860975	8713228REFRP33	Refocus
RR4003	8713228860982	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
R4105	8713228852437	8713228REFRPMIX5P	Infocus
R4111	8713228852499	8713228REFRPMIX5P	Infocus
R4178	8713228864966	8713228REFRPMIX5P	Infocus

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R4179	8713228864973	8713228REFRPMIX5P		Infocus
R4184	8713228865024	8713228REFRPMIX5P		Infocus
R4188	8713228865062	8713228REFRPMIX5P		Infocus
R4190	8713228865086	8713228REFRPMIX5P		Infocus
R6230	8713228860920	8713228REFRPMIX5P		Infocus
R8903	8713228852260	8713228REFRPMIX5P		Infocus

Ready Made Eyewear, Full Rim, Metal

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	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
R1041	8713228860630	8713228REFRM2V		Infocus
R1042	8713228864898	8713228REFRM2V		Infocus
R1043	8713228864904	8713228REFRM2V		Infocus
R8108	8713228846542	8713228REFRM2V		Infocus

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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

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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.