

EU Declaration of conformity

Name and address of manufacturer: EINAR GROUP KFT
Virágos sétány 119, Nagykovácsi
2094, Hungary
Single Registration Number (SRN): HU-MF-000020596

We declare under sole responsibility, that the product
Name of product: SPECTACLE FRAMES / MODELS SEE ANNEX
Brand: OZZIE

PRODUCT FAMILY	BASIC UDI-DI	EMDN CODE
FULL RIM METAL	5996563OFRMECQ	Q02100201
FULL RIM PLASTIC	5996563OFRPLDF	Q02100202
FULL RIM MIXED	5996563OFRMICY	Q02100203
HALF RIM METAL	5996563OHRMED6	Q02100201
HALF RIM PLASTIC	5996563OHRPLDV	Q02100202
HALF RIM MIXED	5996563OHRMIDE	Q02100203
RIMLESS METAL	5996563ORLMEEE	Q02100201
RIMLESS PLASTIC	5996563ORLPLF5	Q02100202
RIMLESS MIXED	5996563ORLMIEN	Q02100203

Nomenclature UMDNS Code: 11667, GMDN Code: 32816
Risk class Class I – non sterile, no measuring function
Conformity assessment procedure pursuant to article 52 (7) for medical devices
conforms with the following regulations:
Regulation (EU) 2017/745 of European Parliament and the Council on medical devices
Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Complies with the European Standard EN ISO 12870:2016 Ophthalmic optics – Spectacle frames – Requirements and test methods

We operate a systematic procedure to monitor the product after placing it on the market.



Nagykovácsi, 18.06.2022
Place and date of issue

ARNOLD TÖLGYESI
MANAGING DIRECTOR



ARNOLD TÖLGYESI
MDR RESPONSIBLE PERSON

ANNEX 1/2

BRAND	MODEL	BASIC UDI-DI	UDI-DI	EMDN CODE
OZZIE	OZ5416A	5996563OFRMECQ	5996563049165	Q02100201
OZZIE	OZ5416B	5996563OFRMECQ	5996563049172	Q02100201
OZZIE	OZ5416D	5996563OFRMECQ	5996563065189	Q02100201
OZZIE	OZ5418A	5996563OHRMED6	5996563049196	Q02100201
OZZIE	OZ5418B	5996563OHRMED6	5996563049202	Q02100201
OZZIE	OZ5418D	5996563OHRMED6	5996563065196	Q02100201
OZZIE	OZ5422	5996563OFRMICY	5996563065202	Q02100203
OZZIE	OZ5422B	5996563OFRMICY	5996563065226	Q02100203
OZZIE	OZ5422C	5996563OFRMICY	5996563065233	Q02100203
OZZIE	OZ5424	5996563OFRMICY	5996563065240	Q02100203
OZZIE	OZ5424B	5996563OFRMICY	5996563065264	Q02100203
OZZIE	OZ5424C	5996563OFRMICY	5996563065271	Q02100203
OZZIE	OZ5466A	5996563OFRMICY	5996563150090	Q02100203
OZZIE	OZ5466B	5996563OFRMICY	5996563150106	Q02100203
OZZIE	OZ5466D	5996563OFRMICY	5996563150120	Q02100203
OZZIE	OZ5468A	5996563OFRMICY	5996563150137	Q02100203
OZZIE	OZ5468C	5996563OFRMICY	5996563150144	Q02100203
OZZIE	OZ5468D	5996563OFRMICY	5996563150151	Q02100203
OZZIE	OZ5472A	5996563OFRMICY	5996563150175	Q02100203
OZZIE	OZ5472B	5996563OFRMICY	5996563150182	Q02100203
OZZIE	OZ5472D	5996563OFRMICY	5996563150205	Q02100203
OZZIE	OZ5482A	5996563OFRMECQ	5996563185153	Q02100201
OZZIE	OZ5482B	5996563OFRMECQ	5996563185160	Q02100201
OZZIE	OZ5482C	5996563OFRMECQ	5996563185177	Q02100201
OZZIE	OZ5482D	5996563OFRMECQ	5996563185184	Q02100201
OZZIE	OZ5484A	5996563OFRMECQ	5996563185191	Q02100201
OZZIE	OZ5484B	5996563OFRMECQ	5996563185207	Q02100201
OZZIE	OZ5484C	5996563OFRMECQ	5996563185214	Q02100201
OZZIE	OZ5488A	5996563OHRMED6	5996563185221	Q02100201
OZZIE	OZ5488B	5996563OHRMED6	5996563185238	Q02100201
OZZIE	OZ5488C	5996563OHRMED6	5996563185245	Q02100201
OZZIE	OZ5893A	5996563OFRPLDF	5996563185252	Q02100202
OZZIE	OZ5893B	5996563OFRPLDF	5996563185269	Q02100202
OZZIE	OZ5893C	5996563OFRPLDF	5996563185276	Q02100202
OZZIE	OZ5893D	5996563OFRPLDF	5996563185283	Q02100202
OZZIE	OZ5895A	5996563OFRPLDF	5996563185290	Q02100202
OZZIE	OZ5895B	5996563OFRPLDF	5996563185306	Q02100202
OZZIE	OZ5895C	5996563OFRPLDF	5996563185313	Q02100202
OZZIE	OZ5895D	5996563OFRPLDF	5996563185320	Q02100202
OZZIE	OZ5897A	5996563OFRMICY	5996563185337	Q02100203

ANNEX 2/2

BRAND	MODEL	BASIC UDI-DI	UDI-DI	EMDN CODE
OZZIE	OZ5897B	5996563OFRMICY	5996563185344	Q02100203
OZZIE	OZ5897C	5996563OFRMICY	5996563185351	Q02100203
OZZIE	OZ5897D	5996563OFRMICY	5996563185368	Q02100203
OZZIE	OZ5903A	5996563OFRPLDF	5996563150250	Q02100202
OZZIE	OZ5903B	5996563OFRPLDF	5996563150267	Q02100202
OZZIE	OZ5903D	5996563OFRPLDF	5996563150281	Q02100202