



EU Declaration of Conformity

with the essential requirements

REGULATIONS OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU)

2017/745 (MDR) of 5 April 2017

Nr: 2/2023

Manufacturer: **3G VISION Sp. z o.o.**
ul. Gajowa 1A
05-091 Ząbki, POLAND

Single Registration Number (SRN): **PL-MF-000036479**

We declare, that this declaration of conformity is issued under the sole responsibility of the manufacturer.

Name of product : **Optical frames (Oprawka okularowa)**
Code GMDN: **32816**

Typ/Models
Type: ZANZARA Eyewear Models: from Z2120 up to Z3000 // from ZCL0001 up to ZCL1000 Basic UDI-DI: 59053172full-rim,metalTL; 59053172half-rim,metalWR; 59053172rimless,metal3M; 59053172vein,metal46; 59053172full,plasticD2; 59053172full-rim,mixedUY; 59053172half-rim,mixedY5
Type: MOISS Eyewear Models: from M1770 up to M3000 // MCL0001 up to MCL0100 Basic UDI-DI: 59053172full-rim,metalTL; 59053172half-rim,metalWR; 59053172rimless,metal3M; 59053172vein,metal46; 59053172full,plasticD2; 59053172full-rim,mixedUY; 59053172half-rim,mixedY5
Type: CIVETTA Eyewear Models: from C2048 up to C3000 Basic UDI-DI: 59053172full-rim,metalTL; 59053172half-rim,metalWR; 59053172rimless,metal3M; 59053172vein,metal46; 59053172full,plasticD2; 59053172full-rim,mixedUY; 59053172half-rim,mixedY5
Type: ZARDO Eyewear Models: from ZD0001 up to ZD1000 // from ZDCL0001 up to ZDCL0100 Basic UDI-DI: 59053172full-rim,metalTL; 59053172half-rim,metalWR; 59053172rimless,metal3M; 59053172vein,metal46; 59053172full,plasticD2; 59053172full-rim,mixedUY; 59053172half-rim,mixedY5
Type: SIENA Eyewear Models: from SN0001 up to SN1000 // from SNCL0001 up to SNCL0100 Basic UDI-DI: 59053172full-rim,metalTL; 59053172half-rim,metalWR; 59053172rimless,metal3M; 59053172vein,metal46; 59053172full,plasticD2; 59053172full-rim,mixedUY; 59053172half-rim,mixedY5

Intended use of the product:

The role of the spectacle frames is to fix the lenses in front of the eyes in such a way that the correction conditions are met, that is, the correct distance between the lenses and the eyes, the correct centering of the lenses and their correct inclination are kept.

Classification: Class 1, rule 1 in accordance with Annex VIII to REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on medical devices, amendments to Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC

I declare with full and sole responsibility that the products specified above comply with the requirements of the REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on medical devices, amendments to Directive 2001/83 / EC, Regulation (EC) No. 178 / 2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC and the following standards:

- PN-EN ISO 15223-1
- PN-EN ISO 12870
- PN-EN ISO 10993-1
- PN-EN ISO 14971

We declare, that this declaration of conformity UE is issued under the sole responsibility of the manufacturer.

Place: Ząbki, 6.07.2023 r.
CEO – Piotr Grzelak

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