


The declaration of conformity is issued under the sole responsibility of the manufacturer:

**OPTOR S.A.U.** Quintana i Millars 2, Nave-G 08940 Cornellà de Llobregat, Barcelona, España

Regulation (EU) 2017/745 of the European Parliament and of the Council, of April 5 2017 on medical devices.

Regulation (EU) 2016/425 of the European Parliament and of the Council, of March 9 2016 on personal protective equipment.

The undersigned declares, under his/her sole responsibility, that the product:

**PRODUCT** EYEGLOSS FRAMES/EYEAND FACE PROTECTOR  
**INTENDED USE** Suppot and containment of ophthalmic lenses for correction of refractive errors and eye protection  
**BRAND**   
**SNR** ES-MF-000030664  
**BASIC UDI-DI** 8445266PEGASO0FBD  
**CODE EMDN** Q02100202  
**CODE UMDNS** 11-667 Gafas/Eyeglasses  
**MODEL** ORGANIK  
**REFERENCE** 158  
**VARIANTS**

DESCRIPTION		EAN
158.03 Variant with prescription lens	Hermetic	8445266003310
158.08 Variant with prescription lens	Hermetic with Band	8445266002900
158.05 Variant with plano lens	Hermetic	8436010322986
158.09 Variant with plano lens	Hermetic with Band	8436010322962
158.01 Variant with prescription lens	Without Foam	8445266003303
158.04 Variant with plano lens	Without Foam	8436010322962

COMPLIES WITH THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS OF THE REGULATION:

**Regulation (EU) 2017/745 Medical Devices Regulation**

Classification (Rule): CLASS I (Rule 1)

**Regulation (EU) 2016/425 Personal Protective Equipment**

Classification: CATEGORY II

Standards used for the showing compliance with the essential requirements in the specified regulations:

**EN 166:2001, EN 170:2002, EN 172:1994/A1:2000/A2:2001**

**EN ISO 12870:2018, EN ISO 21987:2018, EN ISO 14889:2013/A1:2017, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 15223-1:2021**

For the PPE covered by this declaration, the Notified Body has carried out the EU type examination (module B) and issued the EU type certificate no.

EU Type Certificate	Issued by	Notified Body	Certificate date	Valid until
19/2134/04/0161	AITEX Asociación de Investigación de la Industria Textil Carretera Banyeres 10, 03802 Alcoy (Alicante)	0161	31/01/2024	21/09/2026

Barcelona, 31/01/2024

**OPTOR, S.A.U.**  
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