

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/EYE AND FACE PROTECTOR  
Support and containment of ophthalmic lenses

**INTENDED USE** for correction of refractive errors and eye protection

**BRAND** **PEGASO**

**SNR** ES-MF-000030664

**BASIC UDI-DI** 8445266PEGASO0FBD

**CODE EMDN** Q02100202

**CODE UMDNS** 11-667 Gafas/Eyeglasses

**MODEL** ORGANIK-HERMETIC PRO

**REFERENCE** 211

VARIANTS	NAME	DESCRIPTION	EAN
211.03	HERMETIC PRO	Clear lens with UV filter	8445266005666
211.01	ORGANIK PRO	Rx-able with lenses of different materials and filters	8445266005604
211.02	HERMETIC PRO	Rx-able with lenses of different materials and filters	8445266005611

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

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

Classification (Rule): CLASS I (Rule 1)

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

**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 ISO 16321-1:2022**

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
26/09750/00/0161/B	AITEX Asociación de Investigación de la Industria Textil Carretera Banyeres 10, 03802 Alcoy (Alicante)	0161	24/03/2026	24/03/2031

Barcelona, 24/03/2026

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