

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  
**INTENDED USE** Support and containment of ophthalmic lenses 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  
**REFERENCE** 158  
**VARIANTS**

| DESCRIPTION                           |                    | EAN           |
|---------------------------------------|--------------------|---------------|
| 158.04 Variant with plano lens        | Without Foam       | 8436010322962 |
| 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 |
| 158.03 Variant with prescription lens | Hermetic           | 8445266003310 |
| 158.08 Variant with prescription lens | Hermetic with Band | 8445266002900 |

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 |
|---------------------|--|---------------|------------------|-------------|
| 19/2134/05/0161     | AITEX<br>Asociación de Investigación de la Industria Textil<br>Carretera Banyeres 10, 03802 Alcoy (Alicante) | 0161          | 21/09/2025       | 21/09/2030  |

Barcelona, 21/09/2025

**OPTOR, S. A.U.**  
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 C.I.F.: A-08634917

Iván Gorina Torrents, CEO OPTOR S.A.U  
 Declaration of Conformity n.º: 158EPIPS.V5.21092025