# DECLARATION OF CONFORMITY

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** | READING GLASSES (PRESBYOPIA)/PERSONAL PROTECTIVE EQUIPMENT |
| **INTENDED USE** | Glasses for the correction of presbyopia. Near vision and reading and eye protection |
| **SNR** | ES-MF-000030664 |
| **BASIC UDI-DI** | 8445266PEGASO0FBD |
| **CODE EMDN** | Q02100202 |
| **CODE UMDNS** | 11-667 Gafas/Eyeglasses |
| **MODEL** | WORK & FUN |
| **REFERENCE** | 125 |

| **VARIANTS** | **NAME** | **DESCRIPTION** | **EAN** |
|---|---|---|---|
| Ref. 125.010 | Mod. WORK&FUN +1.00D | Ready-to-wear prescription glasses. | 8445266003099 |
| Ref. 125.015 | Mod. WORK&FUN +1.50D | Ready-to-wear prescription glasses. | 8445266003105 |
| Ref. 125.020 | Mod. WORK&FUN +2.00D | Ready-to-wear prescription glasses. | 8445266003112 |
| Ref. 125.025 | Mod. WORK&FUN +2.50D | Ready-to-wear prescription glasses. | 8445266003129 |
| Ref. 125.030 | Mod. WORK&FUN +3.00D | Ready-to-wear prescription glasses. | 8445266003136 |

*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 14139:2010, 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 166:2001**

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** |
|---|---|---|---|---|
| 19/1430/01/0161 | AITEX<br>Asociación de Investigación de la Industria Textil<br>Carretera Banyeres 10, 03802 Alcoy (Alicante) | 0161 | 10/05/2024 | 10/05/2029 |

Barcelona, 10/05/2024

OPTOR, S. A.U.
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Iván Gorina Torrents, CEO OPTOR S.A.U

*Declaration of Conformity n.º: 125EPIPS.V1.10052024*