

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 **PEGASO**
SNR ES-MF-000030664
BASIC UDI-DI 8445266PEGASO0FBD
CODE EMDN Q02100202
CODE UMDNS 11-667 Gafas/Eyeglasses
MODEL NORMAL
REFERENCE 9R
VARIANTS

DESCRIPTION

EAN

9R46.01 Variant with prescription lens	8445266003273
9R50.01 Variant with prescription lens	8445266003280
9R50.02 Variant with prescription lens	8445266003297
9R Variant with plano lens	8436010310013

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

ISO 12870:2016, ISO 14889:2003, 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
21/4559/00/0161	AITEX Asociación de Investigación de la Industria Textil Carretera Banyeres 10, 03802 Alcoy (Alicante)	0161	30/09/2021	30/09/2026

Barcelona, 30/09/2021

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: 9REPIPS.V0.30092021