

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.

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 DUAL

REFERENCE 169

VARIANTS

DESCRIPTION

EAN

169.010 Variant with reading glasses lens	+1.0 Diop	8445266002580
169.015 Variant with reading glasses lens	+1.5 Diop	8445266002627
169.020 Variant with reading glasses lens	+2.0 Diop	8445266002665
169.025 Variant with reading glasses lens	+2.5 Diop	8445266002702
169.030 Variant with reading glasses lens	+3.0 Diop	8445266002740
169.01 Variant with prescription lens		8445266003143

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 166:2001, EN 170:2002

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

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
19/1562/01/0161	AITEX Asociación de Investigación de la Industria Textil Carretera Banyeres 10, 03802 Alcoy (Alicante)	0161	08/03/2024	08/03/2029

Barcelona, 08/03/2024

OPTOR, S.A.U.
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