

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	
SNR	ES-MF-000030664
BASIC UDI-DI	8445266PEGASO0FBD
CODE EMDN	Q02100202
CODE UMDNS	11-667 Gafas/Eyeglasses
MODEL	AGUILA
REFERENCE	140-159
VARIANTS	

DESCRIPTION	EAN
159.01 Variant with prescription lens	8445266003235
140.01 Variant with prescription lens	8445266003211
140.02 Variant with plano lens	8436010322160

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
19/1493/01/0161	AITEX Asociación de Investigación de la Industria Textil Carretera Banyeres 10, 03802 Alcoy (Alicante)	0161	31/05/2024	31/05/2029

Barcelona, 31/05/2024

OPTOR, S.A.U.
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