

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

Support and containment of ophthalmic lenses

INTENDED USE 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	NAME	DESCRIPTION	EAN
Ref. 140.01	Mod. AGUILA	Rx-able with lenses of different materials and filters	8445266003211
Ref. 159.01	Mod. AGUILA	Rx-able with lenses of different materials and filters	8445266003235

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 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, EN 170:2002, EN 172:1994/A1:2000/A2:2001**

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
19/1493/01/0161	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

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