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	EYEGLASS FRAMES/EYE AND FACE PROTECTOR
INTENDED USE	Support 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	EUROPA
REFERENCE	2009

VARIANTS	**NAME**	**DESCRIPTION**	**EAN**
2009.01	EUROPA	Rx-able with lenses of different materials	8445266003259

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**

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
25/08013/00/0161/B	AITEX Asociación de Investigación de la Industria Textil Carretera Banyeres 10, 03802 Alcoy (Alicante)	0161	23/01/2025	23/01/2030

Barcelona, 23/01/2025

OPTOR, S. A.U.
C/. Quintana i Millars, 2, nave G
Tel. 93 204 81 10
08940 CORNELLÀ DE LLOBREGAT
C.I.F.: A-08634917

Iván Gorina Torrents, CEO OPTOR S.A.U

Declaration of Conformity n.º: 2009EPIPS.V0.23012025