



## EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer MEDOP.

<b>PPE Identification</b>	Type	Eye protection – Prescription spectacles		
	References	HELSE neutral 211 brown (914544), 212 blue (914545) and 213 black (914546).  HELSE prescription 211 brown (H211 MARR UNIC), 212 blue (H212 AZUL UNIC) and 213 black (H213 NEGR UNIC).		
	Batch			
<b>Manufacturer</b>	MEDOP c/ Bruno Mauricio Zabala, 16-4º izq – 48003 Bilbao – Vizcaya - Spain www.medop.es			
<b>Object of the declaration</b>	PPE eye protector with neutral and prescription lenses made of polycarbonate that protects against artificial blue light and UV.			
<b>Relevant Union harmonisation legislation</b>	Regulation (EU) 2016/425 Regulation (EU) 2017/475 RD 1591/2009			
<b>Relevant harmonised standards</b>	EN 166:2001 and EN 170:2002			
<b>PPE category</b>	II			
<b>Medical device class</b>	I			
<b>Notified Body that performed the EU type-examination (Module B)</b>	AITEX instituto tecnológico textil (No 0161) Plaza Emilio Sala, 1. 03801 Alcoy (Alicante) Spain.			
<b>Certificate reference</b>	22/4899/00/0161			
<b>Conformity Assessment Procedure</b>	Not Apply <input checked="" type="checkbox"/>	Module C2 <input type="checkbox"/>	Module D <input type="checkbox"/>	

Bilbao, on 4<sup>th</sup> March 2022



Inés Gómez-Rubiera  
Legal Representative