



EU DECLARATION OF CONFORMITY

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

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| PPE Identification | Type | Eye protection – Prescription spectacles | | |
| | References | HELSE CareyeOffice: 211 brown (914544), 212 grey (914545) and 213 black (914546). CareyeIndustry: 211 brown (914605), 212 grey (914606) and 213 black (914607) CareyeRX: 211 brown (H211 MARR UNIC), 212 grey (H212 GRIS UNIC) and 213 black (H213 NEGR UNIC). | | |
| | Batch | | | |
| Manufacturer | MEDOP c/ Bruno Mauricio Zabala, 16-4º izq – 48003 Bilbao – Vizcaya - Spain www.medop.es | | | |
| Object of the declaration | PPE eye protector with neutral and prescription lenses made of polycarbonate that protects against artificial blue light and UV. | | | |
| Relevant Union harmonisation legislation | Regulation (EU) 2016/425 Regulation (EU) 2017/475 RD 1591/2009 | | | |
| Relevant harmonised standards | EN 166:2001 and EN 170:2002 | | | |
| PPE category | II | | | |
| Medical device class | I | | | |
| Notified Body that performed the EU type-examination (Module B) | AITEK instituto tecnológico textil (No 0161) Plaza Emilio Sala, 1. 03801 Alcoy (Alicante) Spain. | | | |
| Certificate reference | 22/4899/01/0161 | | | |
| Conformity Assessment Procedure | Not Apply <input checked="" type="checkbox"/> | Module C2 <input type="checkbox"/> | Module D <input type="checkbox"/> | |

Bilbao, on 9th August 2022



Inés Gómez-Rubiera
Legal Representative