



**CERTOTTICA**

**Istituto Italiano per la Certificazione dei prodotti Ottici Srl**  
**Zona Industriale Villanova**  
**I - 32013 Longarone BL**

Tel.: ++39 437 573157 Fax: ++39 437 573131 E-Mail: info@certottica.it



PRD N°142B  
Membro degli Accordi di Mutuo Riconoscimento  
EA, IAF e ILAC  
Signatory of EA, IAF and ILAC  
Mutual Recognition Agreements

## EU TYPE-EXAMINATION CERTIFICATE

no: AC 11103 Rev.5

Pursuant to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016,

**CERTOTTICA Srl**

**Italian Institute for the certification of optical products**  
**Notified body under PPE Regulation with identification number: 0530**

considering application for EU type-examination no. **19002** submitted on **08/01/2019**

### CERTIFIES THAT

the following personal protective equipment type

**Personal eye protector - Spectacles and goggle**  
**XTREME - XTREME HYBRID**

submitted by

**MEDOP S.A.**

**C/Bruno Mauricio Zabala, 16-4° - 48003 Bilbao - Vizcaya - SPAIN**

meet the essential health and safety requirements which apply to it.

Description of the personal protective equipment model, references to the standards, test results and description of the CE marking placed on the equipment are described on pages 2, 3 and 4 of this document.

First issued on: **30/12/2011**

Renewal or revision date: **21/06/2019**

Expiry date: **23/08/2023**

Longarone, **21/06/2019**

Certification Services Manager  
(Giorgio Sommariva)

**Longarone**

**S.C.R.L.**

This document has no. 4 numbered pages.

**1. Description of the Personal Protective Equipment**

Identification of the PPE: XTREME - XTREME HYBRID  
 Trade name: Medop  
 Kind of equipment: Personal eye protector - Spectacles and goggle  
 Ocular Material: Polycarbonate, CR39 or Mineral glass  
 Frame Material: Polycarbonate, TPR and Nylon + EVA  
 In compliance with Standard(s): EN 166:2001 and /  
 PPE Category: II  
 Field(s) of use: Protection against high-speed particles at extremes of temperature - Low energy (PC lenses);  
 Increased robustness/Basic use (CR39 and mineral glass lenses); Protection against optical radiation -  
 Ultraviolet filters - EN 170 (Clear PC lenses); Protection against optical radiation - Sunglare filters for  
 industrial use - EN 172 (Solar Grey PC and Solar Grey CR39 lenses); Protection against droplets of liquids;  
 Resistance to surface damage by fine particles; Resistance to fogging of oculars (plano PC lenses).

**Note:** The present EU type-examination Certificate is the fifth revision of the previous EC type-examination certificate issued by Certottica on 30/12/2011 with number AC 11103. The first revision, issued on 27/06/2014, added the headbands like alternative retention system and removed the Propionate frame material. The second revision, issued on 13/10/2017, added the small frame size and added, for the Clear PC lenses, the requirements of: protection against high speed particles at extremes of temperature, protection against optical radiation and resistance to fogging. The third revision, issued on 24/08/2018, converted the EC type-examination certificate into an EU type-examination certificate and added the Solar Grey PC lens variant. The fourth revision, issued on 09/11/2018, added the goggle configuration and the requirement of protection against droplets of liquids. This fifth revision adds the CR39 solar grey lens variant. Eye-protector may be in spectacles configuration (with temples or headband) - code XTREME or goggle configuration (with headband and gasket) - code XTREME HYBRID. Both configurations are in two size (small and medium) and has five lens variants: Clear plano or prescription PC lenses (single-vision from +8 to -8 D; bifocal from +7 with addition power 3,0 to -7 with addition power 3,0 D; progressive from +6 with addition power 3,0 to -6 with addition power 3,0 D), Clear plano or prescription CR39 lenses (single-vision from +8 to -8 D; bifocal from +7 with addition power 3,0 to -7 with addition power 3,0 D; progressive from +6 with addition power 3,25 to -6 with addition power 3,25 D), Clear plano or prescription mineral glass lenses (single-vision from +8 to -8 D; bifocal from +6 with addition power 3,0 to -6 with addition power 3,0 D; progressive from +7 with addition power 2,75 to -7 with addition power 2,75 D), Solar Grey plano PC lenses and Solar Grey plano or prescription CR39 lenses (single-vision from +8 to -8 D; bifocal from +7 with addition power 3,0 to -7 with addition power 3,0 D; progressive from +6 with addition power 3,25 to -6 with addition power 3,25 D).

Manufacturer's name: MEDOP S.A.  
 Manufacturer's address: C/Bruno Mauricio Zabala, 16-4° - 48003 Bilbao - Vizcaya - SPAIN  
 Authorised representative's name: /  
 Authorised representative's address: /  
 Certificate's holder: MEDOP S.A.  
 Holder's address: C/Bruno Mauricio Zabala, 16-4° - 48003 Bilbao - Vizcaya - SPAIN



**2. Levels of protection offered by the PPE**

Applicable harmonised standards/technical specifications:

EN 166:2001 - Personal eye-protection - Specifications

EN 167:2001 - Personal eye-protection - Optical test methods

EN 168:2001 - Personal eye-protection - Non-optical test methods

EN 170:2002 - Personal eye-protection - Ultraviolet filters - Transmittance requirements and recommended use

EN 172:1994/A1:2000/A2:2001 - Personal eye-protection - Sunglare filters for industrial use

Personal protection equipment model:XTREME - XTREME HYBRID

complies with the basic requirements and with the following additional requirements provided for by the harmonised standard(s)/technical specification(s) for the particular use of this PPE in the foreseeable conditions of use :

EN 166:2001 and /

Protection against high-speed particles at extremes of temperature - Low energy (PC lenses);

Increased robustness/Basic use (CR39 and mineral glass lenses);

Protection against droplets of liquids (goggle configuration);

Resistance to surface damage by fine particles;

Resistance to fogging of oculars (plano PC lenses).

Moreover, the personal protection equipment complies with the specific requirements provided for by the connected harmonised standard(s)/technical specification(s) for the particular fields of use:

EN 170 and EN 172

The eye-protector model XTREME - XTREME HYBRID with the Clear PC lenses is designed for protection against optical radiation - ultraviolet filters; The eye-protector model XTREME - XTREME HYBRID with the Solar Grey plano PC and Solar Grey CR39 lens variants is designed for protection against optical radiation - sunglare filters for industrial use.

**3. Test and examinations results are covered by the following test reports:**

CERTOTTICA	110146÷148 - 110152÷157	24/02/2011
CERTOTTICA	113480 ÷ 113483	07/12/2011
CERTOTTICA	141248-249-251-252-253	21/05/2014
CERTOTTICA	142002	13/06/2014
CERTOTTICA	170499-500-503-506	15/03/2017
CERTOTTICA	172121 - 172124	30/06/2017
CERTOTTICA	174096 ÷ 174099	05/10/2017
CERTOTTICA	181597÷599 - 182274÷275	20/05/2018 - 21/06/2018
CERTOTTICA	183776 - 185323	10/08/2018 - 26/10/2018
CERTOTTICA	190033 - 193541÷193542	05/02/2019 - 12/06/2019



**4. The marking elements reproduced on the oculars are the following:**

	Ocular 1	Ocular 2
<b>Variant</b>	<b>Clear PC lenses</b>	<b>2C-1,2</b>
<b>Scale Number</b>	<b>Solar Grey PC lenses</b>	<b>5-2,5</b>
	<b>Clear CR39 and Clear mineral glass lenses</b>	<b>/</b>
	<b>Solar Grey CR39 lenses</b>	<b>/</b>
<b>Manufacturer's Identification</b>	<b>MEDOP</b>	<b>MEDOP</b>
<b>Optical class</b>	<b>1</b>	<b>1</b>
<b>Standard of reference</b>		
<b>Symbol of Mechanical Resistance</b>	<b>FT</b>	<b>S</b>
<b>Resistance to surface damage by fine particles</b>	<b>K</b>	<b>K</b>
<b>Resistance to fogging of oculars (plano PC lenses)</b>	<b>N</b>	<b>/</b>
<b>/</b>	<b>/</b>	<b>/</b>
<b>/</b>	<b>/</b>	<b>/</b>
<b>/</b>	<b>/</b>	<b>/</b>
<b>CE Marking</b>	<b>CE</b>	<b>CE</b>

Marking position: On the front lens side, in the upper central position.

**5. The Marking elements reproduced on the frame are the following:**

<b>Manufacturer's Identification</b>	<b>MEDOP</b>
<b>Reference standard</b>	<b>EN 166</b>
<b>Protection against droplets of liquids (goggle configuration only)</b>	<b>3</b>
<b>Protection against high-speed particles at extremes of temperature - Low energy</b>	<b>FT</b>
<b>/</b>	<b>/</b>
<b>/</b>	<b>/</b>
<b>/</b>	<b>/</b>
<b>CE Marking</b>	<b>CE</b>

Marking position: On the right temple, inner position or moulded on the buckle of the headbands.

**6. Statement for category III PPE:**

**Terms and conditions under which the Certificate is issued**

- a) Marking and instructions have been examined in English. Obtaining and supplying versions in languages accepted by the countries where the product is sold are under the complete responsibility of the Manufacturer or of his authorized representative.
- b) Any changes to the product, to the technical documentation or, in set cases, to the manual or to the quality control procedures, shall be notified in time to Certottica.
- c) The Manufacturer or his authorized representative shall respect the procedures and rules provided for by Certottica for the issuing of the EU type-examination.
- d) Copies of this EU type-examination certificate, supplied to third parties, shall be reproduced in their entirety.
- e) This EU type-examination certificate shall be kept by the Manufacturer to be shown, on request, to the market surveillance authorities.
- f) This EU type-examination certificate remains property of Certottica, which can ask it to be returned if any of the above mentioned conditions is not respected.

