



## **DECLARACIÓN DE CONFORMIDAD**

El fabricante **MEDOP** con domicilio en C/ Zabala, 16 - 48003 BILBAO (Vizcaya), declara que el EPI:

- Gafa ZION Policarbonato Clear Antiempañante
- Gafa ZION Policarbonato Gris Antiempañante
- Gafa ZION Policarbonato Naranja Antiempañante

es conforme a las disposiciones de la Directiva 89/686/CEE y el Real Decreto 1407/1992, y es idéntico al EPI objeto del **CERTIFICADO CE de TIPO nº 3064** expedido por INSPEC como Organismo Europeo de Control Notificado con el nº 0194.

En Bilbao a 10 de *Julio* de 2017

Representante Legal



Inés Gómez-Rubiera



## Application for Certification - Own Brand Manufacturer

Declaration of Undertaking.

We hereby confirm the following: -

The own brand PPE subject to the current application is physically identical to the original product.

Only product fully compliant with the original type-examination certificate will be supplied to the own brand manufacturer as the specified model.

We, the original manufacturer, will advise the own brand manufacturer of any changes affecting the validity of either the type-examination certificate and for category III PPE, the article 11 supervision.

Any proposed changes to the product will be sent to both INSPEC and the own brand manufacturer before proceeding with the change.

The original technical file, held by INSPEC, can be used to support the own brand manufacturer's application, including article 11 documents, if applicable.

Both the original manufacturer and own brand manufacturer will inform each other of any incidents involving the products covered by the agreement.

Any changes to either the product, the technical file or the quality assurance documents are identified on page 3 of this application.

For category III PPE – We confirm that the article 11 supervision undertaken by INSPEC / Other notified body covers the products subject to this application.

Where INSPEC is not the article 11 body, we confirm that ..... have been advised of this own brand application and evidence of this advice is attached / included.

### Own Brand Manufacturer.

For and on behalf of: ... CLS – Coelhos Têxteis, Lda

Signed:    
 CLS – Coelhos Têxteis, Lda | NIF: 507 443 249  
R. da Indústria, 100 | 4500-100 Ovar | T: 258 120 300 F: 258 320 309

Name: Miguel Freitas

Position: Quality Manager

Date: 24/07/2017

### Original Manufacturer.

For and on behalf of: ... Esther Garrido ..







Signed: ..... Name: ... Esther Garrido ..

Authorised Signatory

Position: ... Quality and Certification Manager ... Date: . 11st July 2017 .

## Application for Certification - Own Brand Manufacturer

### Changes to Original Certificate / Technical File details:

Item	Information	Comments
<p>Attach new logo here</p> <p>→</p>		
<p>Attached new artwork to be printed on product here</p> <p>→</p>	<p>GREY LENSES</p> <div data-bbox="512 846 1031 1084" style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p><u>Inside left temple</u> 0301014</p> <p><u>Inside right temple</u> CE 5-3,1  <b>field</b> 1F EN</p> </div> <div data-bbox="512 1111 967 1205" style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p><u>Lenses</u> CE FIELD 1F</p> </div> <p>CLEAR LENSES</p> <div data-bbox="416 1406 831 1644" style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p><u>Inside left temple</u> 0301013</p> <p><u>Inside right temple</u> CE  <b>field</b> 1F EN</p> </div> <div data-bbox="416 1727 826 1821" style="border: 1px solid black; padding: 5px;"> <p><u>Lenses</u> CE FIELD 1F</p> </div>	
<p>Authorized representative for own brand certificate; (if appointed).</p>	<p>CLS with brand FIELD</p>	

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Changes to the user information	ATTACHED DOCUMENT	
Changes to the test and inspection plan	NO changes	
Changes to the article 11, A or B, system:	Not apply	
Confirmation of any processing to be performed by the own brand certificate holder, e.g. packaging, marking, labeling, addition of user information.	Marking and User Instruction	

**Note: if no changes are identified, it shall be taken that the original technical file and quality assurance details apply fully to the supply of own brand products.**