



Sunoptic International Ltd.  
79 College Road,  
Harrow, Middlesex  
HA1 1BD, UK

Authorized representative:  
Sunoptic Europe BV  
Neerveld 11  
2550 Kontich, BE

**EC Declaration of conformity**

Dear Sirs,

We, Sunoptic International Ltd., declare under our sole responsibility that products to which this declaration relates are in conformity with the following standards:

Name of Manufacturer (SRN): **SUNOPTIC INTERNATIONAL Ltd. ( GB-MF-000009257)**

Authorized representative (SRN): **Sunoptic Europe BVBA (BE-AR-000003314)**

Product name: **Optical frames – Acetate Mix Fullrim ( models see annex)**

Description of products: **Optical Frames designed to maintain the correct distance between the lenses and alignment relative to each eye.**

Brand Name: **Sunoptic / Montana**

Product identification by : **Name of product on polybag**

Risk class: **Class I – non sterile, no measuring function -according to Rule 1, Chapter III, Annex VIII of the EU Regulation 2017/745**

Conformity assessment procedure: **Pursuant to article 52(7) for medical devices**

Nomenclature : **Code (UMDNS) 11-667, GMDN Code 32816**

Basic UDI-DI : **50558608fra-ace-mix-fr9E**

All products are marked with CE logo. The CE marking on the products and/or their packaging signifies that these have been produced with reference to the technical specifications of the European authorities.

Optical Frames of our production follow the specifications and requirements of the European Regulation on medical devices:

**(EU) 2017/745. Conform EN ISO 12870**

**Regulation (EC) No 1907/2006**

Sunoptic International Ltd.

Belgium, 01.01.2022

Bob Kenter  
Director





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## EG-Konformitätserklärung

Sehr geehrte Damen und Herren,

Wir, Sunoptic International Ltd, erklären in alleiniger Verantwortung, dass die Produkte, auf die sich diese Erklärung bezieht, den folgenden Standards entsprechen:

Name des Herstellers (SRN): **SUNOPTIC INTERNATIONAL Ltd. (GB-MF-000009257)**

Autorisierter Vertreter (SRN): **Sunoptic Europe BVBA (BE-AR-000003314)**

Produktname: **Optische Fassungen – Acetat-Mix-Vollrand (Modelle siehe Anhang)**

Produktbeschreibung: **Optische Rahmen, die den richtigen Abstand zwischen den Linsen und die Ausrichtung relativ zu jedem Auge gewährleisten.**

Markenname: **Sunoptic / Montana**

Produktidentifikation durch : **Produktname auf polybeutel**

Risikoklasse: **Klasse I – unsteril, keine Messfunktion - gemäß Regel 1, Kapitel III, Anhang VIII der EU-Verordnung 2017/745**

Konformitätsbewertungsverfahren: **Gemäß Artikel 52 Absatz 7 für Medizinprodukte**

Nomenklatur: **Code (UMDNS) 11-667, GMDN-Code 32816**

Grundlegende UDI-DI: **50558608fra-ace-mix-fr9E**

Alle Produkte sind mit dem CE-Logo gekennzeichnet. Die CE-Kennzeichnung auf den Produkten und/oder ihrer Verpackung bedeutet, dass diese unter Bezugnahme auf die technischen Spezifikationen der europäischen Behörden hergestellt wurden.

Die von uns hergestellten Brillengestelle entsprechen den Spezifikationen und Anforderungen der europäischen Verordnung über Medizinprodukte:

(EU) 2017/745. Konform mit EN ISO 12870

Verordnung (EG) Nr. 1907/2006

Sunoptic International Ltd.

Belgium, 01.01.2022

Bob Kenter  
Director



**ANNEX**

<b>MODEL+ COLOR</b>	<b>GTIN</b>	<b>MATERIAL</b>	<b>RIM</b>
A56	5055860814620	Acetate - Mix	Fullrim
A56A	5055860814637	Acetate - Mix	Fullrim
A56B	5055860814644	Acetate - Mix	Fullrim
A56C	5055860814651	Acetate - Mix	Fullrim
A56D	5055860814668	Acetate - Mix	Fullrim
A56E	5055860814675	Acetate - Mix	Fullrim
A56F	5055860814682	Acetate - Mix	Fullrim
A56G	5055860814699	Acetate - Mix	Fullrim
A58	5055860814781	Acetate - Mix	Fullrim
A58A	5055860814798	Acetate - Mix	Fullrim
A58B	5055860814804	Acetate - Mix	Fullrim
A58C	5055860814811	Acetate - Mix	Fullrim
A58D	5055860814828	Acetate - Mix	Fullrim
A58E	5055860814835	Acetate - Mix	Fullrim
A58F	5055860814842	Acetate - Mix	Fullrim
A58G	5055860814859	Acetate - Mix	Fullrim
A59	5055860814866	Acetate - Mix	Fullrim
A59A	5055860814873	Acetate - Mix	Fullrim
A59B	5055860814880	Acetate - Mix	Fullrim
A59C	5055860814897	Acetate - Mix	Fullrim
A59D	5055860814903	Acetate - Mix	Fullrim
A59E	5055860814910	Acetate - Mix	Fullrim
A59F	5055860814927	Acetate - Mix	Fullrim
A59G	5055860814934	Acetate - Mix	Fullrim
A60	5055860814941	Acetate - Mix	Fullrim
A60A	5055860814958	Acetate - Mix	Fullrim
A60B	5055860814965	Acetate - Mix	Fullrim
A60D	5055860814989	Acetate - Mix	Fullrim
A60E	5055860814996	Acetate - Mix	Fullrim
A60F	5055860815009	Acetate - Mix	Fullrim
A70	5055860808629	Acetate - Mix	Fullrim
A70A	5055860808636	Acetate - Mix	Fullrim
A70B	5055860808643	Acetate - Mix	Fullrim
A70C	5055860808650	Acetate - Mix	Fullrim
A70D	5055860808667	Acetate - Mix	Fullrim
A70F	5055860808681	Acetate - Mix	Fullrim
A70G	5055860808698	Acetate - Mix	Fullrim
A70H	5055860808704	Acetate - Mix	Fullrim
A71	5055860808711	Acetate - Mix	Fullrim



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A71C	5055860808742	Acetate - Mix	Fullrim
A71D	5055860808759	Acetate - Mix	Fullrim
A71E	5055860808766	Acetate - Mix	Fullrim
A71G	5055860808780	Acetate - Mix	Fullrim
A72	5055860808803	Acetate - Mix	Fullrim
A72A	5055860808810	Acetate - Mix	Fullrim
A72B	5055860808827	Acetate - Mix	Fullrim
A72C	5055860808834	Acetate - Mix	Fullrim
A72D	5055860808841	Acetate - Mix	Fullrim
A72E	5055860808858	Acetate - Mix	Fullrim
A72F	5055860808865	Acetate - Mix	Fullrim
A84	5055860804522	Acetate - Mix	Fullrim
A84A	5055860804539	Acetate - Mix	Fullrim
A84B	5055860804546	Acetate - Mix	Fullrim
A84C	5055860804553	Acetate - Mix	Fullrim
A84D	5055860804560	Acetate - Mix	Fullrim
A84E	5055860804577	Acetate - Mix	Fullrim
A84G	5055860804591	Acetate - Mix	Fullrim
A84H	5055860809367	Acetate - Mix	Fullrim
A85	5055130030781	Acetate - Mix	Fullrim
A85A	5055130090952	Acetate - Mix	Fullrim
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A85C	5055130090976	Acetate - Mix	Fullrim
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A85E	5055130090990	Acetate - Mix	Fullrim
A85F	5055130091003	Acetate - Mix	Fullrim
A85G	5055130091010	Acetate - Mix	Fullrim
A85H	5055130091027	Acetate - Mix	Fullrim
A93	5055130083510	Acetate - Mix	Fullrim
A93A	5055130083527	Acetate - Mix	Fullrim
A93B	5055130083534	Acetate - Mix	Fullrim
A93C	5055130083541	Acetate - Mix	Fullrim
A93D	5055130083558	Acetate - Mix	Fullrim
A93E	5055130083565	Acetate - Mix	Fullrim
A93F	5055130083572	Acetate - Mix	Fullrim
A93G	5055130083589	Acetate - Mix	Fullrim
A93H	5055130083596	Acetate - Mix	Fullrim
A95	5055130083688	Acetate - Mix	Fullrim
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A95B	5055130083701	Acetate - Mix	Fullrim
A95F	5055130083749	Acetate - Mix	Fullrim
A101C	5055130075898	Acetate - Mix	Fullrim



A101F	5055130075928	Acetate - Mix	Fullrim
A101G	5055130075935	Acetate - Mix	Fullrim
A101J	5055130075966	Acetate - Mix	Fullrim
A101K	5055130092239	Acetate - Mix	Fullrim
A101L	5055130092246	Acetate - Mix	Fullrim
A105C	5055130076246	Acetate - Mix	Fullrim
A105D	5055130076253	Acetate - Mix	Fullrim
A105E	5055130076260	Acetate - Mix	Fullrim
A105F	5055130076277	Acetate - Mix	Fullrim
A105G	5055130076284	Acetate - Mix	Fullrim
A106	5055130076314	Acetate - Mix	Fullrim
A106A	5055130076321	Acetate - Mix	Fullrim
A106B	5055130076338	Acetate - Mix	Fullrim
A106C	5055130076345	Acetate - Mix	Fullrim
A106D	5055130076352	Acetate - Mix	Fullrim
A106E	5055130076369	Acetate - Mix	Fullrim
A167	5055130065080	Acetate - Mix	Fullrim
A167A	5055130065097	Acetate - Mix	Fullrim
A167B	5055130065103	Acetate - Mix	Fullrim
A167C	5055130065110	Acetate - Mix	Fullrim
A167D	5055130065127	Acetate - Mix	Fullrim
A167E	5055130069217	Acetate - Mix	Fullrim
A167F	5055130069224	Acetate - Mix	Fullrim
A167G	5055130069231	Acetate - Mix	Fullrim
AC1	5055860842135	Acetate - Mix	Fullrim
AC1A	5055860842142	Acetate - Mix	Fullrim
AC1B	5055860842159	Acetate - Mix	Fullrim
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AC1E	5055860842197	Acetate - Mix	Fullrim
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AC2B	5055860842227	Acetate - Mix	Fullrim
AC2C	5055860842234	Acetate - Mix	Fullrim
AC2D	5055860842241	Acetate - Mix	Fullrim
AC2E	5055860842692	Acetate - Mix	Fullrim
AC2F	5055860864946	Acetate - Mix	Fullrim
AC2G	5055860864953	Acetate - Mix	Fullrim
AC3	5055860842708	Acetate - Mix	Fullrim
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AC3B	5055860842722	Acetate - Mix	Fullrim
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AC3E	5055860842753	Acetate - Mix	Fullrim
AC3F	5055860842760	Acetate - Mix	Fullrim
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AC5F	5055860864991	Acetate - Mix	Fullrim
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AC8I	5055860864687	Acetate - Mix	Fullrim
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AC9F	5055860864700	Acetate - Mix	Fullrim
AC9G	5055860864717	Acetate - Mix	Fullrim
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AC10B	5055860860375	Acetate - Mix	Fullrim
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AC12C	5055860860528	Acetate - Mix	Fullrim
AC12D	5055860860535	Acetate - Mix	Fullrim
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AC13B	5055860850031	Acetate - Mix	Fullrim
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AC14	5055860848069	Acetate - Mix	Fullrim
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AC14B	5055860848083	Acetate - Mix	Fullrim
AC14C	5055860848090	Acetate - Mix	Fullrim
AC14D	5055860848106	Acetate - Mix	Fullrim
AC14E	5055860848113	Acetate - Mix	Fullrim
AC14F	5055860848120	Acetate - Mix	Fullrim
AC14G	5055860848137	Acetate - Mix	Fullrim
AC15	5055860839432	Acetate - Mix	Fullrim
AC15A	5055860839449	Acetate - Mix	Fullrim
AC15B	5055860839456	Acetate - Mix	Fullrim
AC15C	5055860840056	Acetate - Mix	Fullrim
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AC15E	5055860840070	Acetate - Mix	Fullrim
AC15F	5055860845730	Acetate - Mix	Fullrim
AC16	5055860838909	Acetate - Mix	Fullrim
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AC16D	5055860838954	Acetate - Mix	Fullrim
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AC18G	5055860845624	Acetate - Mix	Fullrim
AC19	5055860839081	Acetate - Mix	Fullrim
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AC19B	5055860839104	Acetate - Mix	Fullrim
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AC19D	5055860839128	Acetate - Mix	Fullrim
AC19E	5055860839135	Acetate - Mix	Fullrim
AC19F	5055860845631	Acetate - Mix	Fullrim
AC19G	5055860845648	Acetate - Mix	Fullrim
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AC21B	5055860836134	Acetate - Mix	Fullrim
AC21C	5055860836141	Acetate - Mix	Fullrim
AC21D	5055860836158	Acetate - Mix	Fullrim
AC21E	5055860836165	Acetate - Mix	Fullrim
AC22	5055860836059	Acetate - Mix	Fullrim



AC22A	5055860836066	Acetate - Mix	Fullrim
AC22B	5055860836073	Acetate - Mix	Fullrim
AC22C	5055860836080	Acetate - Mix	Fullrim
AC22D	5055860836097	Acetate - Mix	Fullrim
AC22E	5055860836103	Acetate - Mix	Fullrim
AC22F	5055860845686	Acetate - Mix	Fullrim
AC22G	5055860845693	Acetate - Mix	Fullrim
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AC23H	5055860845723	Acetate - Mix	Fullrim
AC24	5055860835441	Acetate - Mix	Fullrim
AC24A	5055860835458	Acetate - Mix	Fullrim
AC24B	5055860835465	Acetate - Mix	Fullrim
AC24C	5055860835472	Acetate - Mix	Fullrim
AC24D	5055860835489	Acetate - Mix	Fullrim
AC24E	5055860835496	Acetate - Mix	Fullrim
AC24F	5055860835502	Acetate - Mix	Fullrim
AC24G	5055860835519	Acetate - Mix	Fullrim
AC25	5055860835366	Acetate - Mix	Fullrim
AC25A	5055860835373	Acetate - Mix	Fullrim
AC25B	5055860835380	Acetate - Mix	Fullrim
AC25C	5055860835397	Acetate - Mix	Fullrim
AC25D	5055860835403	Acetate - Mix	Fullrim
AC25E	5055860835410	Acetate - Mix	Fullrim
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AC25G	5055860835434	Acetate - Mix	Fullrim
AC26	5055860835281	Acetate - Mix	Fullrim
AC26A	5055860835298	Acetate - Mix	Fullrim
AC26B	5055860835304	Acetate - Mix	Fullrim
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AC26E	5055860835335	Acetate - Mix	Fullrim
AC26F	5055860835342	Acetate - Mix	Fullrim
AC26G	5055860835359	Acetate - Mix	Fullrim
AC27	5055860835205	Acetate - Mix	Fullrim
AC27A	5055860835212	Acetate - Mix	Fullrim

AC27B	5055860835229	Acetate - Mix	Fullrim
AC27C	5055860835236	Acetate - Mix	Fullrim
AC27D	5055860835243	Acetate - Mix	Fullrim
AC27E	5055860835250	Acetate - Mix	Fullrim
AC27F	5055860835267	Acetate - Mix	Fullrim
AC27G	5055860835274	Acetate - Mix	Fullrim
AC29	5055860835083	Acetate - Mix	Fullrim
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AC29B	5055860835106	Acetate - Mix	Fullrim
AC29C	5055860835113	Acetate - Mix	Fullrim
AC29D	5055860835120	Acetate - Mix	Fullrim
AC29E	5055860835137	Acetate - Mix	Fullrim
AC32	5055860834840	Acetate - Mix	Fullrim
AC32A	5055860834857	Acetate - Mix	Fullrim
AC32B	5055860834864	Acetate - Mix	Fullrim
AC32C	5055860834871	Acetate - Mix	Fullrim
AC32D	5055860834888	Acetate - Mix	Fullrim
AC32E	5055860834895	Acetate - Mix	Fullrim
AC32F	5055860834901	Acetate - Mix	Fullrim
AC32G	5055860834918	Acetate - Mix	Fullrim
AC32H	5055860834925	Acetate - Mix	Fullrim
AC33	5055860832501	Acetate - Mix	Fullrim
AC33A	5055860832518	Acetate - Mix	Fullrim
AC33B	5055860832525	Acetate - Mix	Fullrim
AC33C	5055860832532	Acetate - Mix	Fullrim
AC33D	5055860832549	Acetate - Mix	Fullrim
AC33E	5055860832556	Acetate - Mix	Fullrim
AC33F	5055860832563	Acetate - Mix	Fullrim
AC34	5055860830606	Acetate - Mix	Fullrim
AC34A	5055860830613	Acetate - Mix	Fullrim
AC34B	5055860830620	Acetate - Mix	Fullrim
AC34C	5055860830637	Acetate - Mix	Fullrim
AC34D	5055860832471	Acetate - Mix	Fullrim
AC34E	5055860832488	Acetate - Mix	Fullrim
AC34F	5055860832495	Acetate - Mix	Fullrim
AC36	5055860832389	Acetate - Mix	Fullrim
AC36A	5055860832396	Acetate - Mix	Fullrim
AC36B	5055860832402	Acetate - Mix	Fullrim
AC36C	5055860832419	Acetate - Mix	Fullrim
AC36D	5055860832426	Acetate - Mix	Fullrim
AC36E	5055860832433	Acetate - Mix	Fullrim
AC41	5055860827330	Acetate - Mix	Fullrim

AC41A	5055860827347	Acetate - Mix	Fullrim
AC41B	5055860827354	Acetate - Mix	Fullrim
AC41C	5055860827361	Acetate - Mix	Fullrim
AC41D	5055860827378	Acetate - Mix	Fullrim
AC41E	5055860827385	Acetate - Mix	Fullrim
AC41F	5055860830972	Acetate - Mix	Fullrim
AC41G	5055860830989	Acetate - Mix	Fullrim
AC43	5055860827453	Acetate - Mix	Fullrim
AC43A	5055860827460	Acetate - Mix	Fullrim
AC43B	5055860827477	Acetate - Mix	Fullrim
AC43C	5055860827484	Acetate - Mix	Fullrim
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MA61D	5055860841206	Acetate - Mix	Fullrim
MA61E	5055860841213	Acetate - Mix	Fullrim



Sunoptic International Ltd.  
79 College Road,  
Harrow, Middlesex  
HA1 1BD, UK

Authorized representative:  
Sunoptic Europe BV  
Neerveld 11  
2550 Kontich, BE

MA61F	5055860845747	Acetate - Mix	Fullrim
MA64A	5055860827989	Acetate - Mix	Fullrim
MA64B	5055860827996	Acetate - Mix	Fullrim
MA64D	5055860828016	Acetate - Mix	Fullrim
MA64E	5055860828023	Acetate - Mix	Fullrim
MA65	5055860828030	Acetate - Mix	Fullrim
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MA65D	5055860828078	Acetate - Mix	Fullrim
MA65E	5055860828085	Acetate - Mix	Fullrim
MA65F	5055860828092	Acetate - Mix	Fullrim
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MA67	5055860821925	Acetate - Mix	Fullrim
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MA67E	5055860821970	Acetate - Mix	Fullrim
MA67F	5055860821987	Acetate - Mix	Fullrim
MA67G	5055860821994	Acetate - Mix	Fullrim

