



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: **Ready readers metal mix (models see annex)**

Description of products: **Ready readers designed to maintain the correct distance between the lenses and alignment relative to each eye with the lenses to facilitate reading**

Brand Name: **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 : **50558608rea-met-mixTJ**

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 14139

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: **Ready Readers Metall Mix (Modelle siehe Anhang)**

Produktbeschreibung: **Bereite Lesegeräte, die darauf ausgelegt sind, den korrekten Abstand zwischen den Linsen und die Ausrichtung relativ zu jedem Auge mit den Linsen beizubehalten, um das Lesen zu erleichtern**

Markenname: **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 : **50558608rea-met-mixTJ**

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 14139

Verordnung (EG) Nr. 1907/2006

Sunoptic International Ltd.
Belgium, 01.01.2022

Bob Kenter
Director



ANNEX:

MODEL+ COLOR	GTIN	MATERIAL	RIM
BOX681.00	5055860829730	Metal - Mix	Rimless
BOX681.50	5055860829747	Metal - Mix	Rimless
BOX682.00	5055860829754	Metal - Mix	Rimless
BOX682.50	5055860829761	Metal - Mix	Rimless
BOX683.00	5055860829778	Metal - Mix	Rimless
BOX683.50	5055860829785	Metal - Mix	Rimless
BOX68A1.00	5055860829792	Metal - Mix	Rimless
BOX68A1.50	5055860829808	Metal - Mix	Rimless
BOX68A2.00	5055860829815	Metal - Mix	Rimless
BOX68A2.50	5055860829822	Metal - Mix	Rimless
BOX68A3.00	5055860829839	Metal - Mix	Rimless
BOX68A3.50	5055860829846	Metal - Mix	Rimless
BOX68B1.00	5055860829853	Metal - Mix	Rimless
BOX68B1.50	5055860829860	Metal - Mix	Rimless
BOX68B2.00	5055860829877	Metal - Mix	Rimless
BOX68B2.50	5055860829884	Metal - Mix	Rimless
BOX68B3.00	5055860829891	Metal - Mix	Rimless
BOX68B3.50	5055860829907	Metal - Mix	Rimless
BOX68C1.00	5055860829914	Metal - Mix	Rimless
BOX68C1.50	5055860829921	Metal - Mix	Rimless
BOX68C2.00	5055860829938	Metal - Mix	Rimless
BOX68C2.50	5055860829945	Metal - Mix	Rimless
BOX68C3.00	5055860829952	Metal - Mix	Rimless
BOX68C3.50	5055860829969	Metal - Mix	Rimless
BOX68D1.00	5055860829976	Metal - Mix	Rimless
BOX68D1.50	5055860829983	Metal - Mix	Rimless
BOX68D2.00	5055860829990	Metal - Mix	Rimless
BOX68D2.50	5055860830002	Metal - Mix	Rimless
BOX68D3.00	5055860830019	Metal - Mix	Rimless
BOX68D3.50	5055860830026	Metal - Mix	Rimless
HBLF540.00	5055860861730	Metal - Mix	Fullrim
HBLF541.00	5055860861747	Metal - Mix	Fullrim
HBLF541.50	5055860861754	Metal - Mix	Fullrim
HBLF542.00	5055860861761	Metal - Mix	Fullrim
HBLF542.50	5055860861778	Metal - Mix	Fullrim
HBLF543.00	5055860861785	Metal - Mix	Fullrim
HBLF543.50	5055860861792	Metal - Mix	Fullrim

HBLF54A0.00	5055860861808	Metal - Mix	Fullrim
HBLF54A1.00	5055860861815	Metal - Mix	Fullrim
HBLF54A1.50	5055860861822	Metal - Mix	Fullrim
HBLF54A2.00	5055860861839	Metal - Mix	Fullrim
HBLF54A2.50	5055860861846	Metal - Mix	Fullrim
HBLF54A3.00	5055860861853	Metal - Mix	Fullrim
HBLF54A3.50	5055860861860	Metal - Mix	Fullrim
HMR541.00	5055860861877	Metal - Mix	Fullrim
HMR541.50	5055860861884	Metal - Mix	Fullrim
HMR542.00	5055860861891	Metal - Mix	Fullrim
HMR542.50	5055860861907	Metal - Mix	Fullrim
HMR543.00	5055860861914	Metal - Mix	Fullrim
HMR543.50	5055860861921	Metal - Mix	Fullrim
HMR54A1.00	5055860861938	Metal - Mix	Fullrim
HMR54A1.50	5055860861945	Metal - Mix	Fullrim
HMR54A2.00	5055860861952	Metal - Mix	Fullrim
HMR54A2.50	5055860861969	Metal - Mix	Fullrim
HMR54A3.00	5055860861976	Metal - Mix	Fullrim
HMR54A3.50	5055860861983	Metal - Mix	Fullrim
HMR54S1.00	5055860861990	Metal - Mix	Fullrim
HMR54S1.50	5055860862003	Metal - Mix	Fullrim
HMR54S2.00	5055860862010	Metal - Mix	Fullrim
HMR54S2.50	5055860862027	Metal - Mix	Fullrim
HMR54S3.00	5055860862034	Metal - Mix	Fullrim
HMR54S3.50	5055860862041	Metal - Mix	Fullrim
HMR581.00	5055860853902	Metal - Mix	Fullrim
HMR581.50	5055860853919	Metal - Mix	Fullrim
HMR582.00	5055860853926	Metal - Mix	Fullrim
HMR582.50	5055860853933	Metal - Mix	Fullrim
HMR583.00	5055860853940	Metal - Mix	Fullrim
HMR583.50	5055860853957	Metal - Mix	Fullrim
HMR58A1.00	5055860853964	Metal - Mix	Fullrim
HMR58A1.50	5055860853971	Metal - Mix	Fullrim
HMR58A2.00	5055860853988	Metal - Mix	Fullrim
HMR58A2.50	5055860853995	Metal - Mix	Fullrim
HMR58A3.00	5055860854008	Metal - Mix	Fullrim
HMR58A3.50	5055860854015	Metal - Mix	Fullrim
HMR631.00	5055860854145	Metal - Mix	Fullrim
HMR631.50	5055860854152	Metal - Mix	Fullrim
HMR632.00	5055860854169	Metal - Mix	Fullrim
HMR632.50	5055860854176	Metal - Mix	Fullrim
HMR633.00	5055860854183	Metal - Mix	Fullrim

HMR633.50	5055860854190	Metal - Mix	Fullrim
HMR63A1.00	5055860854206	Metal - Mix	Fullrim
HMR63A1.50	5055860854213	Metal - Mix	Fullrim
HMR63A2.00	5055860854220	Metal - Mix	Fullrim
HMR63A2.50	5055860854237	Metal - Mix	Fullrim
HMR63A3.00	5055860854244	Metal - Mix	Fullrim
HMR63A3.50	5055860854251	Metal - Mix	Fullrim
HMR63B1.00	5055860854268	Metal - Mix	Fullrim
HMR63B1.50	5055860854275	Metal - Mix	Fullrim
HMR63B2.00	5055860854282	Metal - Mix	Fullrim
HMR63B2.50	5055860854299	Metal - Mix	Fullrim
HMR63B3.00	5055860854305	Metal - Mix	Fullrim
HMR63B3.50	5055860854312	Metal - Mix	Fullrim
MR101.00	5055130026357	Metal - Mix	Halfrim
MR101.50	5055130026364	Metal - Mix	Halfrim
MR102.00	5055130026371	Metal - Mix	Halfrim
MR102.50	5055130026388	Metal - Mix	Halfrim
MR103.00	5055130026395	Metal - Mix	Halfrim
MR103.50	5055130026401	Metal - Mix	Halfrim
MR10A1.00	5055130026425	Metal - Mix	Halfrim
MR10A1.50	5055130026432	Metal - Mix	Halfrim
MR10A2.00	5055130026449	Metal - Mix	Halfrim
MR10A2.50	5055130026456	Metal - Mix	Halfrim
MR10A3.00	5055130026463	Metal - Mix	Halfrim
MR10A3.50	5055130026470	Metal - Mix	Halfrim
MR10B1.00	5055130026494	Metal - Mix	Halfrim
MR10B1.50	5055130026500	Metal - Mix	Halfrim
MR10B2.00	5055130026517	Metal - Mix	Halfrim
MR10B2.50	5055130026524	Metal - Mix	Halfrim
MR10B3.00	5055130026531	Metal - Mix	Halfrim
MR10B3.50	5055130026548	Metal - Mix	Halfrim
MR10C1.00	5055130026562	Metal - Mix	Halfrim
MR10C1.50	5055130026579	Metal - Mix	Halfrim
MR10C2.00	5055130026586	Metal - Mix	Halfrim
MR10C2.50	5055130026593	Metal - Mix	Halfrim
MR10C3.00	5055130026609	Metal - Mix	Halfrim
MR10C3.50	5055130026616	Metal - Mix	Halfrim
MR631.00	5055860845891	Metal - Mix	Fullrim
MR631.50	5055860845907	Metal - Mix	Fullrim
MR632.00	5055860845914	Metal - Mix	Fullrim
MR632.50	5055860845921	Metal - Mix	Fullrim
MR633.00	5055860845938	Metal - Mix	Fullrim

MR633.50	5055860845945	Metal - Mix	Fullrim
MR63A1.00	5055860845952	Metal - Mix	Fullrim
MR63A1.50	5055860845969	Metal - Mix	Fullrim
MR63A2.00	5055860845976	Metal - Mix	Fullrim
MR63A2.50	5055860845983	Metal - Mix	Fullrim
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MR63A3.50	5055860846003	Metal - Mix	Fullrim
MR63B1.00	5055860846010	Metal - Mix	Fullrim
MR63B1.50	5055860846027	Metal - Mix	Fullrim
MR63B2.00	5055860846034	Metal - Mix	Fullrim
MR63B2.50	5055860846041	Metal - Mix	Fullrim
MR63B3.00	5055860846058	Metal - Mix	Fullrim
MR63B3.50	5055860846065	Metal - Mix	Fullrim
MR63C1.00	5055860846072	Metal - Mix	Fullrim
MR63C1.50	5055860846089	Metal - Mix	Fullrim
MR63C2.00	5055860846096	Metal - Mix	Fullrim
MR63C2.50	5055860846102	Metal - Mix	Fullrim
MR63C3.00	5055860846119	Metal - Mix	Fullrim
MR63C3.50	5055860846126	Metal - Mix	Fullrim
MR991.00	5055130087167	Metal - Mix	Fullrim
MR991.50	5055130087174	Metal - Mix	Fullrim
MR992.00	5055130087181	Metal - Mix	Fullrim
MR992.50	5055130087198	Metal - Mix	Fullrim
MR993.00	5055130087204	Metal - Mix	Fullrim
MR993.50	5055130087211	Metal - Mix	Fullrim
MR99A1.00	5055130087288	Metal - Mix	Fullrim
MR99A1.50	5055130087235	Metal - Mix	Fullrim
MR99A2.00	5055130087242	Metal - Mix	Fullrim
MR99A2.50	5055130087259	Metal - Mix	Fullrim
MR99A3.00	5055130087266	Metal - Mix	Fullrim
MR99A3.50	5055130087273	Metal - Mix	Fullrim
MR99B1.00	5055130087280	Metal - Mix	Fullrim
MR99B1.50	5055130087297	Metal - Mix	Fullrim
MR99B2.00	5055130087303	Metal - Mix	Fullrim
MR99B2.50	5055130087310	Metal - Mix	Fullrim
MR99B3.00	5055130087327	Metal - Mix	Fullrim
MR99B3.50	5055130087334	Metal - Mix	Fullrim
MR99C1.00	5055130087341	Metal - Mix	Fullrim
MR99C1.50	5055130087358	Metal - Mix	Fullrim
MR99C2.00	5055130087365	Metal - Mix	Fullrim
MR99C2.50	5055130087372	Metal - Mix	Fullrim
MR99C3.00	5055130087389	Metal - Mix	Fullrim

MR99C3.50	5055130087396	Metal - Mix	Fullrim
NR21.00	5055860836936	Metal - Mix	Fullrim
NR21.50	5055860836943	Metal - Mix	Fullrim
NR22.00	5055860836950	Metal - Mix	Fullrim
NR22.50	5055860836967	Metal - Mix	Fullrim
NR23.00	5055860836974	Metal - Mix	Fullrim
NR23.50	5055860836981	Metal - Mix	Fullrim
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NR2A1.50	5055860837001	Metal - Mix	Fullrim
NR2A2.00	5055860837018	Metal - Mix	Fullrim
NR2A2.50	5055860837025	Metal - Mix	Fullrim
NR2A3.00	5055860837032	Metal - Mix	Fullrim
NR2A3.50	5055860837049	Metal - Mix	Fullrim
NR2B1.00	5055860837056	Metal - Mix	Fullrim
NR2B1.50	5055860837063	Metal - Mix	Fullrim
NR2B2.00	5055860837070	Metal - Mix	Fullrim
NR2B2.50	5055860837087	Metal - Mix	Fullrim
NR2B3.00	5055860837094	Metal - Mix	Fullrim
NR2B3.50	5055860837100	Metal - Mix	Fullrim
RF251.00	5055130069606	Metal - Mix	Fullrim
RF251.50	5055130069613	Metal - Mix	Fullrim
RF252.00	5055130069620	Metal - Mix	Fullrim
RF252.50	5055130069637	Metal - Mix	Fullrim
RF253.00	5055130069644	Metal - Mix	Fullrim
RF253.50	5055130069651	Metal - Mix	Fullrim
RF25A1.00	5055130069668	Metal - Mix	Fullrim
RF25A1.50	5055130069675	Metal - Mix	Fullrim
RF25A2.00	5055130069682	Metal - Mix	Fullrim
RF25A2.50	5055130069699	Metal - Mix	Fullrim
RF25A3.00	5055130069705	Metal - Mix	Fullrim
RF25A3.50	5055130069712	Metal - Mix	Fullrim
RF25B1.00	5055130091836	Metal - Mix	Fullrim
RF25B1.50	5055130091843	Metal - Mix	Fullrim
RF25B2.00	5055130091850	Metal - Mix	Fullrim
RF25B2.50	5055130091867	Metal - Mix	Fullrim
RF25B3.00	5055130091874	Metal - Mix	Fullrim
RF25B3.50	5055130091881	Metal - Mix	Fullrim
TR11.00	5055860834604	Metal - Mix	Fullrim
TR11.50	5055860834611	Metal - Mix	Fullrim
TR12.00	5055860834628	Metal - Mix	Fullrim
TR12.50	5055860834635	Metal - Mix	Fullrim
TR13.00	5055860834642	Metal - Mix	Fullrim



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TR13.50	5055860834659	Metal - Mix	Fullrim
TR1A1.00	5055860834666	Metal - Mix	Fullrim
TR1A1.50	5055860834673	Metal - Mix	Fullrim
TR1A2.00	5055860834680	Metal - Mix	Fullrim
TR1A2.50	5055860834697	Metal - Mix	Fullrim
TR1A3.00	5055860834703	Metal - Mix	Fullrim
TR1A3.50	5055860834710	Metal - Mix	Fullrim
TR1B1.00	5055860834727	Metal - Mix	Fullrim
TR1B1.50	5055860834734	Metal - Mix	Fullrim
TR1B2.00	5055860834741	Metal - Mix	Fullrim
TR1B2.50	5055860834758	Metal - Mix	Fullrim
TR1B3.00	5055860834765	Metal - Mix	Fullrim
TR1B3.50	5055860834772	Metal - Mix	Fullrim
TR1C1.00	5055860834789	Metal - Mix	Fullrim
TR1C1.50	5055860834796	Metal - Mix	Fullrim
TR1C2.00	5055860834802	Metal - Mix	Fullrim
TR1C2.50	5055860834819	Metal - Mix	Fullrim
TR1C3.00	5055860834826	Metal - Mix	Fullrim
TR1C3.50	5055860834833	Metal - Mix	Fullrim