

Declaration of conformity

Spectacle Frames

Medical device class I



Name of manufacturer	Name	MASUNAGA OPTICAL MFG. CO., LTD.
	Address	4-15 Imaichi-cho
	Postal code	918-8152
	City, Country	Fukui-city, Fukui, Japan

We declare under sole responsibility that the product

Name of product	Brand	MASUNAGA
Optical frames without prescription lenses (see appendix)		MASUNAGA since 1905
		MASUNAGA designed by Kenzo Takada
		MASUNAGA K3
		Kazuo Kawasaki
		KOOKI

Nomenclature	GMDN Code 32816, EMDN Code Q02100203
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Risk class	Class I – non sterile, no measuring function
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conforms with the following regulations:

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

Complies with European standard EN ISO 12870

We operate a quality management system based on ISO 13485 adapted to the medical device risk class I. This quality management system for medical devices is part of the regular on-site audits which we allow and support completely.

This product is in compliance with the Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Place and date of issue

Signature of Inspector
Minoru Takeuchi
Position : Sales Manager

Model Name	Model Name	Model Name
000	036	071
001	037 APOLLO	072
002	038 DIANA	073
003	039	074
004	040	075
005	041	076
006	042	077
007	043	078
008	044	079
009	045	080
010	046	081
011	047	082
012	048	083
013	049	084
015	050	085
016	051	086
017	052	087
018	053	088
019	054	089
020	055	090
021	056	091
022	057	092
023	058	093
024	059	094
025	060	095
026	061	096
027	062	097
028	063	098
029	064	099
030	065	100
031	066	101
032	067	102
033	068	103
034	069	
035	070	

Model Name	Model Name	Model Name
GMS-07	GMS-122T	GMS-813
GMS-08	GMS-123	GMS-813L
GMS-09	GMS-124	GMS-814
GMS-12	GMS-125	GMS-815
GMS-13	GMS-126T	GMS-816
GMS-14	GMS-196T	GMS-817
GMS-15	GMS-196TN	GMS-818
GMS-16	GMS-197TS	GMS-819
GMS-17	GMS-198T	GMS-820
GMS-18	GMS-198TS	GMS-821
GMS-19	GMS-199T	GMS-822
GMS-22	GMS-199TS	GMS-823
GMS-35	GMS-200T	GMS-824
GMS-103	GMS-200TS	GMS-825
GMS-103+	GMS-201T	GMS-826
GMS-104	GMS-202T	GMS-827
GMS-105	GMS-203	GMS-828
GMS-106	GMS-303	GMS-829
GMS-107	GMS-396BT	GMS-830
GMS-108	GMS-396BT+	GMS-831
GMS-109	GMS-396BTS	GMS-832
GMS-110	GMS-800	GMS-833
GMS-112	GMS-801	GMS-834
GMS-113	GMS-801S	
GMS-114	GMS-802	
GMS-115	GMS-803	
GMS-116	GMS-804	
GMS-117	GMS-805	
GMS-118	GMS-806	
GMS-118S	GMS-807	
GMS-119	GMS-808	
GMS-119TS	GMS-809	
GMS-119TSN	GMS-810	
GMS-120TS	GMS-811	
GMS-121TS	GMS-812	

Model Name	Model Name
AERON	JULIET
ALICIA	LEMPICKA
ASTORIA	LENOX
AUDREY	LEX
AURORA	LIBERTY
BASIE	LOEWY
BAY BRIDGE	MADISON
BILLIE	MARGOT
BIRD	MET
BRADBURY	MIES
Chord A	MIES II
Chord C	MONK
Chord D	NY LIFE
Chord E	OCEAN DRIVE
Chord F	ODETTE
Chord G	RADIO CITY
COCO	RHAPSODY
COLINS	STRATUS
CONCORDE I	SWAN LAKE
CONCORDE II	SWING
DAILY NEWS	TANGO
DAIY	TINSELTOWN
DATE LINE	URBANITE
DESKEY	VAN ALEN
ELLA	VIVI
ELLINGTON	WALDORF
EMPIRE I	WRIGHT
EMPIRE II	
EON	
FLATIRON	
FULLER	
FUTURA	
GISELLE	
GRACE	
GREENWICH	



MASUNAGA

designed by

Kengo Takeda

Model Name Model Name

Alcor Sedna

Altair Spica

Anemone Vega

Apus

Atria

Avior

Capella

Caph

Caster

Comet

Cygnus

Hadar

Iris

Juno

Kiri

Leo

Lepus

Libra

Lynx

Lyra

Mimosa

Mira

Mizar

Morning Glory

Orchid

Orion

Pictor

Procyon

Quince

Rigel

Rindo

Sakura

MASUNAGA | KE

Model Name

Alya

Aquila

Aster

Centaurus

Ceres

Deneb

Inazuma

Lilac

Pearl

Suzu

Taka

Taurus