

## Declaration of conformity

Sunglasses PPE personal protective equipment  
MDR Medical device regulation



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	<b>Brand MASUNAGA</b> <b>MASUNAGA since 1905</b> <b>MASUNAGA designed by Kenzo Takada</b> <b>MASUNAGA   K3</b> <b>Kazuo Kawasaki</b> <b>KOOKI</b>
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PPE risk category	<b>Category I</b>
Frame glazable with power lenses	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

conforms with the following regulations:

Regulation (EU) 2016/425 on personal protective equipment

Complies with European standard EN ISO 12312-1

In case the product is rated glazable, the conformity declaration includes also:

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).

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Place and date of issue

\_\_\_\_\_  
**Person responsible**  
authorized signature  
plus company stamp

<b>Model Name</b>	<b>Model Name</b>	<b>Model Name</b>
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	104
035	070	105

Model Name

GMS-07 CLIP ON

GMS-08

GMS-106

GMS-109-01

GMS-113

GMS-114

GMS-115

GMS-117

GMS-804

GMS-804SP

GMS-805

GMS-822

GMS-824

**Model Name**

BAY BRIDGE

BIRD

COLINS

CONCORDE I

DATE LINE

DIZZY

EMPIRE II

EON

LOEWY

MONK

OCEAN DRIVE

RHAPSODY

SWING

TRANE

VAN ALEN

WRIGHT

MA-9000

MA-9001

MA-9002

MA-9002X

MA-9003

MA-9004

MA-9005

MA-9006

MA-9007

MA-9008

MA-9009



MASUNAGA

designed by

*Kengo Takeda*

Model Name	Model Name
Acrux	Scutum
Altair	Sedna
Amaryllis	Sirius
Atria	Spica
Becrux	Tsuki
Bellatrix	Vega
Botan	Vela
Calla Lily	
Campanule	
Canopus	
Caph	
Comet	
Dahlia	
Dent de lion	
Hercules	
Jet	
Kabuto	
Kiri	
Leo	
Libra	
Lotus	
Lupin	
Lys	
Marigold	
Meteor	
Mira	
Mokko	
Pollux	
Quince	
Regulus	
Rigel	
Ryu	

## **Model Name**

Aoi

Aquila

Centaurus

Genji

Marsic

Misago

Rhea

Suzu

Taka

Tobi