MASUNAGA

MASUNAGA OPTICAL MFG. CO., LTD
4-15, Imaichi-cho, Fukui-city, 918-8152 JAPAN TEL: 0776-38-1027 FAX: 0776-38-5008
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Declaration of conformity

Spectacle Frames Medical device class I

CE

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 since 1905** **MASUNAGA designed by Kenzo Takada** **MASUNAGA | K3**
Nomenclature	**GMDN Code 32816, EMDN Code Q02100203**	
Risk class	**Class I – non sterile, no measuring function**	

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).

The product does not contain any Substances of Very High Concern (SVHC) of the candidate list released by the European Chemicals Agency (ECHA) above a concentration of 0.1% by weight.

Link to ECHA: Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

Fukui, Japan. February 1, 2022
Place and date of issue

Person responsible
authorized signature
plus company stamp