G.A. Yellows Co., Ltd
32-3 Akasaka-cho, Echizen-city, 915-0256, JAPAN

# Declaration of conformity

Spectacle Frames Medical device Class Ⅰ

Name of manufacturer: **G.A. Yellows Co., Ltd**
32-3 Akasaka-cho, Echizen-city, 915-0256, JAPAN

We declare under sole responsibility that the product

Nomenclature : **GMDN Code 32816, EMDN Code Q02100203**

Risk class : Class Ⅰ – non sterile, no measuring function

Name of product : **Brand : YELLOWS PLUS**

Fulfils the requirements of the following standard :
**ISO 12870 : 2018**
**EN 12472 : 2005 + A1 : 2009**
**EN 16128 : 2015**

And conforms with the following European regulations:

CE

**2017/745** of the European Parliament and of the Council on medial devices

**Regulation (EC) No 1907/2006** on the Registration, Evaluation, Authorization 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, Sabae、Japan

11th July 2022
Place and date of issue

Authorized Signature and Company stamp

G.A. Yellows Co., Ltd
32-3 Akasaka-cho, Echizen-city, 915-0256, JAPAN

# Declaration of conformity

CE

Sunglasses PPE personal protective equitpment
MDR Medical device regulation

Name of manufacturer: **G.A. Yellows Co., Ltd**
32-3 Akasaka-cho, Echizen-city, 915-0256, JAPAN

We declare under sole responsibility that the product

Name of product : **Brand : YELLOWS PLUS**

PPE risk category : Category Ⅰ
Frame glazable with power lenses : Yes

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.

**Regulation (EC) No 1907/2006** on the Registration, Evaluation, Authorization 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.
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株式会社 G. A. Yellows之印

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