



**DECLARATION OF CONFORMITY**  
ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

**EU Representative**

SUNGO Europe B.V.  
Fascinatio Boulevard 522,  
Unit 1.7,, 2909 VA Capelle  
aan den IJssel, Netherlands  
SRN: NL-A R- 000000247

**Conformity Assessment**

**Conformity Assessment Procedure**

Annex II+III of Regulation (EU) 2017/745

**Applicable Standards**

EN ISO 14971:2019+A11:2021  
EN ISO 20417:2021  
EN ISO 10993-1:2020  
EN ISO 12870:2018

**Remark**

*The declaration of conformity is valid in connection with the release technical document CE/MDR-SF-02.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer*

**Manufacturer**

Name: WENZHOU HIGO OPTICAL CO., LTD.  
SRN: CN-MF-000022737

Address: 7 Floor, Building 7, Panqian Community,  
Panfeng Village, Wutian Street, Ouhai District,  
Wenzhou City  
ZHEJIANG, CHINA

**Product Information**

Intended purpose: Spectacle frames intended to be fitted with corrective or plano lenses.

Importer: KOOKA spol.s.r.o, Prague, Czechia

Name : DEEJAY

Model: C1100, C1101, 9202, 9203, 9204, 9205, 9206

Basic UDI-DI:

**697473781HG001JB**

Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

**Declaration**

We hereby declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above

温州市海格眼镜有限公司  
WENZHOU HIGO OPTICAL CO., LTD

Signature:

Date: Nov 22 2024

Position: GM

Place: Wenzhou/China