



**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)2017/45

#### 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

Importer: KOOKA spol.s.r.o

Name : DEEJAY

Model: DE2-001, DE2-002, DE2-004, 9109, 9110, TB13030, TB13031, ZF2002, ZS2-001, ZS2-003, ZS2-004, 1000, 112, 901, 907, 912, 915, 918, 921, 938, 939, 952, 948, 955, 956, 957, 962, 963, 964, 969, DE2014, DE2015, DE2016, DE2017, DE2021, 1001, 1002

Basic UDI-DI:

**697473781HG001JB**

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

### Declaration

We here with 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: Aug 27 2024

Position:GM

Place: Wenzhou/China