Verze 2

DECLARATION OF CONFORMITY

ACCORDING TO(EU)2017/745 MEDICAL DEVICE REGULATION

EU Zástupce

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

Conformity Statement

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:
112.901,902,903,904,907,908,909,910,911,912,913,914,915,916, 918, 920,921,922,923,924,925,926,932,933,938,939,940,944,945, 946,947,948,949,951,952,954,955,956,957,958,959,960,961,962, 963,964,965,967,968,969,970,971,972,1012,1013,1017,1021, J2511,J2512,J2513,9101,9102,9103,9104,9105,9106,9107,9108, 2252，BEP992,BEP991

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: 陈罗

Date: Nov 25 2021

Position:GM

Place: Wenzhou/China