

EU DECLARATION OF CONFORMITY

(in accordance with Regulation (EU) 2017/745 on medical devices, Annex IV, and Regulation (EU) 2016/425 on personal protective equipment)

Manufacturer

Name: WENZHOU HIGO OPTICAL CO.,LTD.

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

SRN: CN-MF-000022737

EU Authorised Representative

Name: SUNGO Europe B.V.

Address: Fascinatio Boulevard 522, Unit 1.7,, 2909 VA Capelle aan den
IJssel, Netherlands

SRN: NL- A R- 000000247

Product Identification

Product Name: Spectacle Frames with Magnetic Clip-On Sun Lenses
"DeeJay"

Models:

2510, 2511, 2512, 2513, 1000, 1001, 1002, 1012, 1013, 1021, 103, 104,
106, 112, 2251-001, 2251, 2252, 2252-001, 2592, 2595, 74, 83, 901,
902, 903, 904, 907, 908, 909, 910, 9101, 9102, 9103, 9104, 9105,
9106, 9107, 9108, 9109, 911, 9110, 912, 914, 915, 918, 9202, 9203,
9204, 9205, 9206, 921, 9217, 9218, 922, 9223, 923, 9234, 9235, 9237,
9239, 924, 9242, 9247, 925, 926, 9265, 9266, 932, 933, 938, 939, 940,
945, 946, 947, 948, 949, 95, 950, 951, 952, 955, 956, 957, 960, 962,
963, 964, 968, 969, 970, 971, 972, 975, 976, 977, 991, 992, BEP991,
BEP992, C1100, C1101, C1108, C1113, C1114, C1115, C1116, C1118,
C1119, C1120, C1124, C2403, C2406, C2408, C6114, DE2001, DE2002,
DE2004, DE2014, DE2015, DE2016, DE2017, DE2021, HF2404, HG6076,
HG6105, HG6107, TB13030, TB13031, TTRC9030, TTRC9056, TTRC9059,
ZF2002, ZS2001, ZS2003, ZS2004

Basic UDI-DI:

697473781HG001JB

Device Description

Clip-on spectacle frames consisting of an ophthalmic spectacle frame supplied with removable magnetic clip-on sun lenses ("sun clip"). The spectacle frame is intended to hold corrective or plano ophthalmic lenses. When fitted with the supplied sun clip, the product also provides protection against solar radiation.

Frames are manufactured from metal and/or plastic materials and are in direct contact with intact skin.

Intended Purpose

Spectacle frames intended to be fitted with corrective or plano lenses for vision correction or eye protection. When fitted with the supplied sun clip, the product also provides protection against solar radiation.

Classification

Class I medical device (non-sterile, without measuring function) in accordance with Rule 1, Annex VIII of Regulation (EU) 2017/745

When equipped with the supplied sun clip, the product also falls within the scope of Regulation (EU) 2016/425 as personal protective equipment.

Conformity Assessment Procedure

The conformity assessment procedure has been carried out in accordance with Article 52(7) of Regulation (EU) 2017/745.

The manufacturer has drawn up the technical documentation in accordance with Annex II and Annex III of the Regulation.

Declaration

We hereby declare under our sole responsibility that the above-mentioned products comply with the applicable requirements of:

- Regulation (EU) 2017/745 on medical devices (MDR); and
- Regulation (EU) 2016/425 on personal protective equipment (PPE), when equipped with the supplied magnetic sun clip.

This declaration is issued under the sole responsibility of the manufacturer.

Applied Standards

The following harmonised standards and specifications have been applied:

EN ISO 14971:2019+A11:2021

EN ISO 20417:2021

EN ISO 10993-1:2020

EN ISO 12870:2018

EN ISO 12312-1:2022

Additional Information

Place: Wenzhou, China

Date: June. 20TH, 2026

Name:

Position: G. MANAGER

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

Signature: _____

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