TEST REPORT

Applicant: KWIAT
ZLATOWRYH 51B/19
1164 SOFIA
BULGARIA

Attn: EDYTA CWETKOW

Number: HKGH0303285202

Date: Aug 02, 2023

Sample and Information provided by customer :
Item Name : **Spectacle frame**
Quantity : 4 pairs
Country of Origin : China

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Conclusion:
The submitted sample was tested under the following requirements requested by the applicant, subject to the information stated in the remark and attached page(s) for details :

	Requirement	Result
(1)	BS EN ISO 12870 : 2018 Ophthalmic optics - Spectacle frames - Requirements and test methods (also see Note (1) to (6))	Pass

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Decision Rule(s):
When a statement of conformity to a specification or standard is provided on test report, the decision rule shall be applied. For details, please refer to Intertek's "Decision Rule Document" and is available on Intertek's website. https://intertekhk.grd.by/decision-rule-doc..
If decision rule already inhered in the requested specification or standard, Intertek's "Decision Rule Document" is not applicable and indication of "∞" was shown as above table.

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For and on behalf of :
Intertek Testing Services HK Ltd.

Cindy I.K. Chan
Vice President

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(1) Requirements for Spectacle Frames

Test Standard : BS EN ISO 12870:2018 - Ophthalmic optics - Spectacle frames - Requirements and test methods.

Number of samples tested: Two (2) pairs

Note:
1. The test sample was fitted with lenses provided by the applicant.
2. Clause 4.2.3 Nickel release is included in the standard but not covered in the following test results.
3. Spectacle frames shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the health (and safety) of the wearer. The risks posed by substances leaking (migrating) from the device that might come into prolonged contact with the skin shall be reduced by the manufacturer to a practicable minimum and within the limits of any existing regulatory requirement. Special attention shall be given to substance that are know to be allergenic, carcinogenic, mutagenic or toxic to reproduction per Clause 4.2.2 General physiological compatibility.
4. If a spectacle frame is manufactured using materials (e.g. plastics, alloys, coatings or pigments) not previously used in spectacle frame manufacture, the clinical evaluation shall be made according to the appropriate International Standard(s), either using the spectacle frame itself or using studies where the identical material is used in other medical devices per Clause 4.2.4 Clinical evaluation.
5. Measurement of the stated nominal dimensions is made according to ISO 8624 per Clause 4.3 measuring system.
6. Per Clause 4.5, tolerance on screw threads used in the spectacle frame shall conform to ISO 11381.
7. CE marking or UKCA marking is not specified in BS EN ISO 12870:2018. However per Regulation (EU) 2017/745 or UK Medical Devices Regulations 2002, the CE marking or UKCA marking must appear in a visible, legible and indelible form on the device, the instructions for use and the sales packaging respectively.

   It was found that only CE marking marking was provided on the frame.

Clause	Requirement	Result
4.2.1	Construction	P
4.4	Dimensional tolerances on nominal size	P
4.6	Dimensional stability at elevated temperature	P
4.7	Resistance to perspiration	P
4.8	Mechanical stability	
4.8.1	Bridge deformation	P
4.8.2	Lens retention characteristics	P
4.8.3	Endurance	P
4.9	Resistance to ignition	P
4.10	Resistance to optical radiation	P
9	Marking	P (Note 7)
10	Additional information to be supplied by the manufacturer or other person (agent) placing the product on the market	#1

Abbreviation : P = Pass

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Test data:

Clause 4.4 Dimensional tolerances on nominal size

Nominal size	Measured values (mm)	Claimed values (mm)	Limits (mm)
Horizontal boxed lens size	51.98	52	±0.5
Distance between lenses	16.63	17	±0.5
Overall length	139.27	140	±2.0

Clause 4.6 Dimensional stability at elevated temperature

Deformation (mm)	Limits (mm)
-2.4	+6 / -12

Clause 4.8.1 Bridge deformation

Deformation (%)	Limits (%)
0	2

Clause 4.8.3 Endurance

Deformation (mm)	Limits (mm)
0.9	5

Remark:

#1 - The following additional information shall be supplied by the manufacturer of other person placing the product on the market:

(1) Information with respect to particular processing conditions that may be required when fitting lenses or manipulating the spectacle frame for adjustment purposes.

(2) The range available (sizes and colours) including other side lengths available in catalogues.

(3) The following information should be made available upon request:
- (a) Vertical boxed lens size;
- (b) Bridge width;
- (c) Bridge height;
- (d) Effective diameter;
- (e) A list of components that are available separately.

(4) If the manufacturer does not have a registered place of business, the packaging or labelling shall state the name and address of the authorized representative in some countries.

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(5) For spectacle frames intended for children younger than 36 months, warnings be provided regarding the possibility of parts becoming detached or an asphyxiation hazard may require in some countries.

Note: for example, Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, and EN 71-1

(6) For spectacle frames fitted with headbands that help retain the spectacles in the correct position in front of the eyes, the headband shall not be capable of causing a strangulation hazard in some countries.

Note: for example, Directive 2009/48/EC of the European Parliament and of the Council of
18 June 2009 on the safety of toys, and EN 14682.

Date sample received : Jul 07, 2023
Testing period : Jul 07, 2023 to Jul 18, 2023

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End of report

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