EU Declaration of conformity

Name of manufacturer	**MI.OPTICS s.r.o.** **Jindřichova 308** **344 01 Domažlice** **Czech Republic**
Single Registration Number (SRN)	**CZ-MF-000012845**

We declare under sole responsibility that the product:

Name of product	**Spectacle frames FHX**
Trade Name	**Prague**
Model	**8463**
Colors	**001,002,003,004**
Basic UDI-DI	**8596510FHX002U**
Nomenclature	**GMDN Code 32816, EMDN Code Q02100203**
Risk class	**Class I – non sterile, no measuring function**
Conformity assessment procedure	**pursuant to article 52 (7) for medical devices**

Conforms with the following regulations:

- Regulation of the European Parliament and of the Council (EU) 2017/745 on medical devices
- Complies with European standard EN ISO 12870
- Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

We operate a systematic procedure to monitor the product after placing it on the market.

Domažlice, 29.03.2024		
Place and Date of issue	Pavel Linder MDR responsible person	Jiri Kaiser CEO MI.OPTICS s.r.o.