



## EU Declaration of conformity

# MI.OPTICS

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	<b>Spectacle frames FHX</b>
Trade Name	<b>CUBISTA</b>
Model	<b>8650</b>
Colors	<b>T01,T02,T03,T04</b>
Basic UDI-DI	<b>8596510FHX002U</b>
Nomenclature	<b>GMDN Code 32816, EMDN Code Q02100203</b>
Risk class	<b>Class I – non sterile, no measuring function</b>
Conformity assessment procedure	<b>pursuant to article 52 (7) for medical devices</b>

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,  
19.04.2024

Place and Date of issue

Pavel Linder  
MDR responsible person

Jiri Kaiser  
CEO MI.OPTICS s.r.o.