

## **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 CUBISTA

Model **8643** 

Colors **T01,T02,T03,T04,T05** 

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, 19.04.2024

Place and Date of issue

Pavel Linder

MDR responsible person

Jiri Kaiser

CEO MI.OPTICS s.r.o.