



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	Spectacle frames FHX
Trade Name	CUBISTA
Model	8628
Colors	T01, T02, T03
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,
26.04.2024

Place and Date of issue

Pavel Linder
MDR responsible person

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