EU Declaration of conformity

MIOPTICS

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	8348
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, 25.04.2024

Place and Date of issue

Pavel Linder MDR responsible person

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