

CE DECLARATION OF CONFORMITY

Name of manufacturer: KWIAT OOD
 Address of central office: 1164 Sofia, Bulgaria
 Plachkovitsa Str. 1A
 VAT BG130899216
 Actor ID/SRN: BG-MF-000024350

We declare under sole responsibility, that the products SPECTACLE FRAMES with brand: KWIAT, KWIAT CHIC, KWIAT CLIP ON, KWIAT COMFORT, KWIAT EXCLUSIVE, KWIAT JUNIOR, KWIAT TITAN, KWIAT TOP MODELS, ADRIANA ROTH, COSMOLINE, DENI ROTH, VOX.

PRODUCT FAMILY	BASIC UDI-DI	EMDN CODE
KWIAT	380099KWFM	Q02100299
KWIAT CHIC	380099KWCHLL	Q02100299
KWIAT CLIP ON	380099KCLW6	Q02100299
KWIAT COMFORT	380099KCOMFBE	Q02100299
KWIAT EXCLUSIVE	380099KWEXMS	Q02100299
KWIAT JUNIOR	380099KJUNLM	Q02100299
KWIAT TITAN	380099KTFF	Q02100299
KWIAT TOP MODELS	380099KRKWEXRHE	Q02100299
ADRIANA ROTH	380099ARED	Q02100299
COSMOLINE	380099COSMOCG	Q02100299
DENI ROTH	380099DREN	Q02100299
VOX	380099VOXRZ	Q02100299

Nomenclature: UMDNS Code: 11667, GMDN Code: 32816. Risk class: Class I – non sterile, no measuring functions.

Conformity assessment procedure pursuant to article 52 (7) for medical devices conforms to the following regulations:

1. Regulation (EU) 2017/745 of European Parliament and the Council on medical devices.
2. Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
3. Complies with the European Standard EN ISO 12870:2016 Ophthalmic optics - spectacle frames - requirements and test methods.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared: EN ISO 12312-1:2022

The products carry the CE Mark:



Sofia, 01.01.2023

Signed for and on behalf of

CEO KWIAT OOD (Ltd.) Pawel Cwetkow

