



EU Declaration of Conformity

European Communities Council Regulation EU 2017/745 Concerning Medical Devices (MDR)

Manufacturer:

IVKO GmbH
Hauptstrasse 9
56729 Nitz
Germany

We hereby declare that the following mentioned products meet the provisions of the Council Regulation EU 2017/745 covering medical devices. All documentation is controlled and retained on company premises. This declaration of conformity is issued under the sole responsibility of IVKO GmbH.

UDI-DI: Serial Numbers printed on frames

Product: Eyewear (Spectacle Frames)

Condition Supplied: Non-sterile

Classification: Class I under Rule 1 Non-invasive

Conformity Self-Assessment as a class I device

Standards Applied:

- EN ISO 12870:2018
- EN ISO 14971:2020
- EN ISO 10993-1:2009
- EN 1811:2015
- EN 12472:2020
- EN ISO 12311:2015
- EN ISO 12312-1:2015
- Regulation 2016/425 on personal protective equipment
- Regulation (EG) No. 1907/2006 on the registration, evaluation, authorization and restriction of chemicals (REACH)
- Directive 94/62/EG on packing and packing waste
- DIN 58184:2021

Approved By:



Dipl.-Kfm.

K.-U. Lüttgen

Person Responsible for Regulation Compliance (PRRC)

Date of Issue: 09/01/2021