

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: WENZHOU XINYUAN INTERNATIONAL TRADE CO.,LTD
The 3rd Floor of the 3rd Building, N° 248 Zhonghui Road,
Louqiao Street, Ouhai District, Wenzhou, Zhejiang, China

Trademark: Europa Eyewear

European Representative: EUROPA EYEWEAR, S.L.
C/ Manuel Simó, 26 bajo izq. 46007-Valencia (Spain)

SRN: NL-AR-000002066

Trade name: Europa Eyewear

Product name: E1449, E1450, YK152 SPIRO

Intended Use: Optical frames to mount correct lenses

Basic UDI-DI: 697524222XYOFRS

Classification acc. to MDR
Ax. VIII: Class I, Rule 4

Applied Standard & Common Specification: Regulation (EU) 2017/745 on Medical Devices (MDR)

Conformity assessment procedure: Annex II + Annex III of MDR

CE certificate No.: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Manager

2022.5.14


温州市昕源国际贸易有限公司
WENZHOU XINYUAN INTERNATIONAL TRADE CO., LTD.