

EU DECLARATION OF CONFORMITY

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

Manufacturer: Huang Shan JUDE Trading Co. Ltd. Huizhon Avenue, Tunxi District, Huangshan City, Anhui Province, China P.C. 325000. Tel: 0086-577-86083805

Trademark: Europa Eyewear

SRN: Not available yet

Trade name: Europa Eyewear

Product name: E1427,E1428,E1429, E1438, E1439 (Europa Eyewear)

Intended Use: Optical frames to mount correct lenses

Basic UDI: Not available yet

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 N°: 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.

HUANG YINGHE / Commercial manager

Huangshan, 30th September 30, 2021

