

EU DECLARATION OF CONFORMITY

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

Manufacturer: Wenzhou Readsun Optical Co.,Ltd
4F, #1 Building, No.1 Jixian Road,Louqiao Industry Park, Ouhai,
Wenzhou,Zhejiang,China

Trademark: Europa Eyewear

European Representative: Abmed Medical Technology Limited
WorkHub, 51 Bracken Road, Sandyford Business Park, Dublin,
D18 CV48, Ireland

SRN: IE-AR-000043897

Trade name: Europa Eyewear

Product name: E1519, E1520, E1521, E1522, E1523

Intended Use: Optical frames to mount correct lenses

Basic UDI: 0 6976245676369 / 0 6976245676376 / 0 6976245676383
0 6976245676390 / 0 6976245676406

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

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.

Steven / General manager

Wenzhou, Mar.7th.2025

温州瑞尚光学有限公司
WENZHOU READSUN OPTICAL CO.,LTD.

张士伟