

EU DECLARATION OF CONFORMITY

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

Manufacturer: WENZHOU HORIZON OPTICAL CO.,LTD
Floor 5th, Building 2, N° 477, Jiquang Road.Louqiao Street,
Ouhai, Wenzhou, China

Trademark: EUROPA

European
Representative: Humiss International B.V.
Joop Geesinkweg,701 1114AB Amsterdam-Duivendrech

SRN: CN-MF-000017134

Trade name: EUROPA

Product name: E1446 E1546 E1547 E1548
Intended Use: Optical frames to mount correct lenses

Basic UDI: 697504447FRMHQ

**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.

WENZHOU HORIZON OPTICAL CO., LTD
HUANG YINGHE / Commercial manager

温州水平光学有限公司
WENZHOU HORIZON OPTICAL CO.,LTD
April 2026