

# EU DECLARATION OF CONFORMITY

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

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

**Trademark:** **MIA VITALE, EUROPA**

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

**SRN:** CN-MF-000017134

**Trade name:** **MIA VITALE, EUROPA**

**Product name:** **NE189, NE190, NE191, E1446, E1447,E1448**  
**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

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

APRIL, 2024

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