

EU DECLARATION OF CONFORMITY



Declaration of Conformity

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

Manufacturer:

Name: WENZHOU TENGGEN INTERNATIONAL TRADE CO.,LTD
Add: Room 309,6building,Jinhuiapartment,Wenzhou325000,Zhejiang.China
SRN: CN-MF-000046485

European Representative:

Name: Riomavix S.L.
Add: Calle de Almansa 55, 1D, Madrid 28039 Spain
SRN: ES-AR-000001202

Product Name: OPTICAL FRAMES

Product type : Affinity series, Eskymo series

Basic UDI : 6978266190015FB

Intended purpose : Used for glasses matching.

Classification: Class I (According to the Annex VIII,Chapter III,Rule I of Medical Device Class 745/2017).
Conformity Assessment Route: Annex II and III of Regulation (EU) 745/2017.

Applied harmonized standards and Common Specifications:

EN ISO13485:2016 ,ENISO14971:2019 ,ISO10993-1:2018 ,EN ISO10993-5:2009 ,EN ISO10993-10:2013,
EN ISO 12870:2018;

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.

Place of Issue: Wenzhou

Position: General Manager

Signature of Authorized Person: LUCAS JIANG

No.: REP-MDR-20250122Z01

January 22, 2025

DATE



SIGNATURE

Lucas Jiang