EU DECLARATION OF CONFORMITY

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

Manufacturer:

Wenzhou Readsun Optical Co,.Ltd

3F No.281 zhonghui Road, Louqiao Industry Park, Ouhai Economic Development Zone, Wenzhou, Zhejiang, China

Trademark:

Europa Eyewear

European

Representative:

Europa Eyewear S.L.

C/ Manuel Simó, 26 bajo izq. 46007-Valencia (Spain)

SRN:

Not available yet

Trade name:

Europa Eyewear, Mia Vitale

Product name:

E1471, E1474 (Europa Eyewear),

NE152, NE153, NE154 (Mia Vitale)

Intended Use:

Optical frames with clip on lenses

Basic UDI:

697487366YD001RV

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 abovementioned 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.

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

Wenzhou, Sept.18th, 2023