

**Zenka**

**3 avenue de la république**

**39800 POLIGNY**

**SAS au capital de 400 000€**

**Siren : 533679205**

**RCS Lons Le Saunier**

# EU Declaration of Conformity

Manufacturer's Name: ZENKA

Eudamed number : FR-MF-000017824

Manufacturer's Address: 3 avenue de la république, 39800 POLIGNY

Basic UDI-DI:

37014912PCAT6 : Rimless combined frames

37014912CMAS3 : Full rimmed metal frames

37014912CPASC : Full rimmed plastic frames

37014912CCAR5: Full rimmed combined frames

37014912NCASU : Semi rimmed combined frames

37014912CMESB : Children full rimmed metal frames

37014912CCERD : Children full rimmed combined frames

37014912CLMAHC: Metal clips

GMDN code: 32816

Name of the Device (s): All spectacle frames (see products catalog in force) and accessories

Risk Class and Classification Rule: Class I Rule 1

All the optical frames delivered with demo lens, without prescription lenses, distributed by Visioaccess (Fullrim, Semi-rimless, Rimless and combined) are medical devices Class I (in accordance with Annex VIII of the UE Regulation 2017 / 745) and comply with the requirements of UE Regulation 2017 / 745 that apply.

These medical devices comply with the essential safety and performance requirements according to the harmonized standard EN ISO 12870:2018.

This declaration of UE conformity is issued under the sole responsibility of the manufacturer.

Issued at Poligny, on October 16, 2024

Pierre VERRIER

President and CEO

**ZENKA SAS**

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