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:

37014912CMAS3: Full rimmed metal frames

37014912CCAR5: 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 March 29, 2022

Pierre VERRIER

President and CEO

ZENKA SAS

3 Avenue de la République B.P. 10105

39800 POLIGNY CEDEX SIREN 533 679 205 RCS LONS zenka@zenka.fr - Tél: 03.84.73.77.20