

DECLARATION OF C.E. CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745

according to ISO 12870-2016

PRODUCT MANUFACTURER : GROSFILLEY Lunettes
ADDRESS : 10, RUE LEVA
01100 OYONNAX (France)
B.P. 102 – 01103 OYONNAX CEDEX

EXPORTATOR : SOVER OPTICA
ADDRESS : STR. VLAD DRACUL Nr. 35
SECTOR 3
BUCURESTI
ROMANIA, 031195

DECLARE UNDER THEIR RESPONSABILITY THAT THE PRODUCT:

Name :
OPTICAL FRAMES CLASSE MEDICALE 1
Our different lines: Azzaro Paris
Since 1999

Type :
STEEL, MAILLECHORT, TITAN, ACETATE

BASIC UDI-DI :

- 361339AZ0000000000000001WX
- 361339AZ0000000000000002WZ
- 361339AZ0000000000000003X3
- 361339AZ0000000000000004X5
- 361339AZ0000000000000005X7
- 361339AZ0000000000000006X9
- 361339AZ0000000000000007XB

CONFORMS WITH THE REQUISITES OF REGULATIONS

Regulation (EU) 2017/745: *Medical Devices Regulation*

EN 14971: 2001 "Medical devices — Application of risk management to medical devices"

EN980 : *Symbols for use in the labelling of medical devices*

ISO 12870 : *Ophthalmic optics — Spectacle frames — Requirements and test methods*

Classification: *Class I, non-sterile, without a measuring function.*

Date:	16 th of February 2022
Location:	OYONNAX (France)

<i>Name</i>	Conrad LIETOUT	Mr Gérard ANDRUETAN
<i>Signed</i>		
<i>Function</i>	GROSFILLEY Supply Chain Manager	DIRECTION

S.A.S GROSFILLEY LUNETTES
Au capital de 200 000 Euros
10 rue Léva - CS 30506
01117 OYONNAX CEDEX - FRANCE
TEL. 04 74 77 27 34 - FAX 04 74 73 84 65
SIRET 761 200 260 00047 - APE 3250 B