

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: Loris Azzaro
Since 1999

Type :

STEEL, MAILLECHORT, TITAN, ACETATE

BASIC UDI-DI :

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- 361339AZ350000000000002A8
- 361339AZ350000000000003AA
- 361339AZ350000000000004AC
- 361339AZ350000000000005AE
- 361339AZ350000000000006AG
- 361339AZ350000000000007AJ

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: 17th of February 2022

Location: OYONNAX (France)

Name	Conrad LIETOUT	Mr Gerard ANDRUETAN
Signed		
Function GROSFILLEY	Supply Chain Manager	DIRECTION

S.A.S GROSFILLEY LUNETTES

Au capital de 200 000 Euros
10 rue Léva - CS 30506

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