

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: Vicomte A
Since 2010

Type :

STEEL, MAILLECHORT, TITAN, ACETATE

BASIC UDI-DI :

- 361339VA000000000000000001U9
- 361339VA000000000000000002UB
- 361339VA000000000000000003UD
- 361339VA000000000000000004UF
- 361339VA000000000000000005UH
- 361339VA000000000000000006UK
- 361339VA000000000000000007UM

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: 16th of February 2022

Location: OYONNAX (France)

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

GROSFILLEY
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