

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: Chantal Thomass
Since 2012

Type :

STEEL, MAILLECHORT, TITAN, ACETATE

BASIC UDI-DI :

- 361339CT0000000000000001QP
- 361339CT0000000000000002QR
- 361339CT0000000000000003QT
- 361339CT0000000000000004QV
- 361339CT0000000000000005QX
- 361339CT0000000000000006QZ
- 361339CT0000000000000007R3

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:


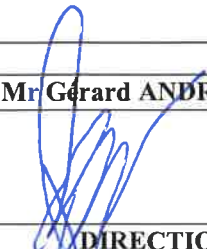
Class I, non-sterile, without a measuring function.

Date:

16th of February 2022

Location:

OYONNAX (France)

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

GROSFILLEY
S.A.S GROSFILLEY LUNETTES

Au capital de 200 000 Euros
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