

# 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: Tehia  
Since 2014

**Type :**  
STEEL, MAILLECHORT, TITAN, ACETATE

**BASIC UDI-DI :**

- 361339T0000000000000000001VY
- 361339T0000000000000000002W2
- 361339T0000000000000000003W4
- 361339T0000000000000000004W6
- 361339T0000000000000000005W8
- 361339T0000000000000000006WA
- 361339T0000000000000000007WC

## 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 <sup>th</sup> of February 2022
Location:	OYONNAX (France)

<b>Name</b>	Conrad LIETOUT	Mr Gérard ANDRUETAN
<b>Signed</b>		
<b>Function</b>	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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