

**S.A.S GROSFILLEY LUNETTES**

10 Rue Léva CS 30506  
01117 OYONNAX Cedex  
FRANCE

# GROSFILLEY

## FRANCE

**SERVICE OPTICIENS FRANCE**

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CAPITAL DE 200 000 EUROS

SIRET 761 200 260 00047

CODE APE 3250B

N° Identification T.V.A FR 20761200260

www.grosfilley.com

**EXPORT DEPARTMENT**

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**EU DECLARATION OF CONFORMITY**

**CONFORMS WITH THE REQUIREMENTS OF REGULATIONS According to Annex II+III of MDR (EU) 2017/745**

- Regulation (EU) 2017/745 : Medical Devices Regulation
- ISO 12870 : Ophthalmic optics – Requirements and test method
- REACH 1907/2006 : Registration, Evaluation, Authorization and restriction of CHemicals
- EN 16128:2015 : Ophthalmic optics. Reference method for the testing of spectacle frames and sunglasses for nickel release

Medical device's name	Type	Basic UDI-DI	Intended purpose	Regulatory classification Code GMDN : 32816
Optical frames classes medical 1 :  <b>TEHIA</b>	Full rim Nylon Rimless Combined	361339T0000000000000001VY 361339T0000000000000002W2 361339T0000000000000003W4 361339T0000000000000004W6 361339T0000000000000005W8 361339T0000000000000006WA 361339T0000000000000007WC	Spectacle frames intended to be associated with corrective lenses	Class I according to rule 1 of Annex VIII of the MDR 2017/745

**EU DECLARATION OF CONFORMITY UNDER THE SOLE RESPONSIBILITY OF**

Manufacturer name	<b>Grosfilley Lunettes</b>
Address	<b>10 Rue Leva, 01100 Oyonnax, France</b>
Date	<b>24/05/2023</b>
Visa	<p><b>GROSFILLEY</b> S.A.S. GROSFILLEY LUNETTES Au Capital de 200 000 € 10 rue Léva – BP 102 01117 OYONNAX CEDEX – FRANCE Tél. 04 74 77 27 34 - Fax 04 74 73 84 65 SIRET 761 200 260 00047 – APE 3250 B</p>
Conrad Lietout Manager Supply Chain	 <i>On behalf of Gérard Andruetan CEO of Grosfilley</i>
Head Office	<b>Grosfilley Lunettes</b>
Single registration number (SRN)	<b>FR-MF-000023866</b>