

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 : AZZARO	Full rim Nylon Rimless Combined	361339AZ000000000000001WX 361339AZ000000000000002WZ 361339AZ000000000000003X3 361339AZ000000000000004X5 361339AZ000000000000005X7 361339AZ000000000000006X9 361339AZ000000000000007XB	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	Grosfilley Lunettes
Address	10 Rue Léva, 01100 Oyonnax, France
Date	24/05/2023
Visa	<p>GROSFILLEY 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 E</p>
Conrad Lietout Manager Supply Chain	 <i>On behalf of Gérard Andruetan CEO of Grosfilley</i>
Head Office	Grosfilley Lunettes
Single registration number (SRN)	FR-MF-000023866