

## UE Declaration of Conformity

CONFORMITY ASSESSMENT PROCEDURE: according to the Annex II + III of MDR (EU) 2017/745

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

**Description of the Product:**


**HENRY JULLIEN** such as Metal Ophtalmic frames

**Class Medical 1 – according to rule 1 of Annex VIII of the MDR 2017/745**

**Basic UDI-DI:**

- **3667094DOUR**
- **3667094PERCEE28**
- **3667094NANO6L**
- **3667094HYBRID4Z**

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

MANUFACTURER NAME	IVISION TECH France SAS
ADDRESS	65 Rue Edouard Branly, 39000 Lons Les Saunier, France.
DATE	28.05.2024
VISA	<b>IVISION TECH FRANCE SAS</b> 65, rue Edouard Branly 39000 LONS LE SAUNIER / FRANCE SIRET 980 002 315 00011 - TVA. FR 07 980 002 315
STEFANO FULCHIR, CEO	
SINGLE REGISTRATION NUMBER (SRN)	FR-MR-000042055