

to: **SOVER OPTICA**

EU DECLARATION

TRIS OTTICA SPA in its capacity as the manufacturer, hereby declares, under its sole responsibility, that the spectacle frames

MODEL: LAMARCA CESELLI

MODEL: LAMARCA FUSIONI

MODEL: LAMARCA INTAGLI

MODEL: LAMARCA MOSAICO

MODEL: LAMARCA POLICROMIE

MODEL: LAMARCA PROFILI

MODEL: LAMARCA SCULTURA

in all their versions (colors and sizes)

are class I medical device (Rule 1 Chapter III of Annex VIII of (EU) Regulation 2017/745), which is intended for use in connection with, in the manufacturing of eyeglasses, ophthalmic lenses for correcting vision problems.

Also declares that they are in conformity with the provisions of (EU) Regulation 2017/745 on Medical Devices and with the standard EN ISO 12870:2018

Furthermore, TRIS OTTICA SPA, **according to comma 7 art. 52 of section 2 of (EU) Regulation 2017/745**, also states under its sole responsibility that as Manufacturer of class I devices, **other than custom-made or investigational devices, declares the conformity of its products by drawing up the EU declaration of conformity** referred to in Article 19, after having drawn up the technical documentation referred to in Annexes II and III and **that the involvement of the notified body in those procedures shall be limited to the following cases:**

- (a) in the case of devices placed on the market in a sterile state, to aspects relating to the demonstration, achievement and maintenance of the sterile state;
- (b) in the case of devices with a measuring function, to aspects relating to the conformity of the devices with the metrological requirements;
- (c) in the case of reusable surgical instruments, to aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance, functional testing and the instructions for use thereof.

Therefore, **since neither case (a), nor case (b), nor case (c) applies**, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued according to the point 8 of Annex IV of (EU) Regulation 2017/745) is not applicable.

Segusino, 2024-08-07

TRIS OTTICA SpA
Nicola Belli
CEO



Unique manufacturer registration number: 805116679

Basic UDI-DI: 805116679ACETAV