

Visottica Comotec is keen on offering reliable NOSE PADS complying with international standards FOR PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT. The latest development, MEM® material, is positioned at even a higher level than what is requested by regulations of the optical field.

The nose pads shells are in direct and prolonged contact with the skin, making them a critical point of any frame. Visottica Comotec efforts are dedicated to protect the health of the final consumer by certifying the compliance of every material used, as well as securing the responsibility of the different members of the supply chain (manufacturers, brands and distributors, etc.).

## OUR NOSEPADS ARE IN COMPLIANCE WITH:

**REACH:** Famous European comprehensive regulations of all chemicals.

**CPSIA:** US Regulation limiting the content of many common substances (such as Phtalates and Lead).

**PROP. 65:** Californian Regulation which regulates substances officially listed by California. Particularly in relation to BpA, our nose pads perfectly comply with "Safe Harbor Level" of 3 µg/day, under which clear and reasonable warnings are not needed. Due to the nickel content of the galvanized insert, GPIE personalized pads are an exception and do not comply with this regulation.

**CONFLICT MATERIALS:** Regulating the use of minerals coming from countries affected by conflicts or extensive human rights violations.

**ISO 12870:** Major requirements for unglazed spectacle frames designed for use with all prescription lenses. About NOSE PADS, the standard defines the method for testing the resistance to: perspiration, ignition, optical radiation. It defines the requirements for products intended to come into direct and prolonged contact with the skin (such as NOSE PADS shell):

The **BIOCOMPATIBILITY** of new materials for NOSE PAD shell is guaranteed by passing three tests of ISO 10993 - "Biological Evaluation of Medical Devices": Cytotoxicity, Irritation and Sensitization. Concerning historical materials that have been used for years in the market, for which there are no clear evidence of allergic reactions, the BIOCOMPATIBILITY is verified with only Cytotoxicity test.

## OUR NOSEPADS ARE EXCEEDING MANDATORY REGULATIONS

We offer **Medical Grade Material** shells which grant higher safety and biocompatibility standards, following USP "CLASS VI" (US Pharmacopeia Standard).

Our **MEM® - Medical Ecofriendly Material** is exceeding all above standards, in particular it is:

**Recyclable**

**Energy saver**

**Medical Grade**

**Respecting Humans and the Environment**

And it guarantees compliance with most of **Restricted Substance Lists** of the biggest players in the market.

More detailed information and declarations are available on our website <https://www.visotticacomotec.com/download/compliance-declaration/>