

Biocompatibility of Cellulose Acetate sheets produced by Mazzucchelli 1849

According to Regulation (EU) 2017/745 on medical devices, frames with ophthalmic lenses fall under the category of medical devices class I.

In order to evaluate the biocompatibility of these medical devices a test protocol must be followed, as defined by the ISO 10993 standard which states its procedure.

Both the Regulation and the standard take into consideration many factors for a medical device to be considered biocompatible:

- Tradition of use;
- Scientific literature;
- In vitro or in vivo tests.

It should be noted that both the standard and the Regulation provide that it is the manufacturer of the medical device who is responsible for the certification of his product and not the producer of the raw material or semi-finished products.

Mazzucchelli, which has always been attentive to comply with all the regulatory and safety requirements of its materials, wanted to anticipate market considerations through an assessment of its products in the supply conditions, in such a way as to be able to support, with these evaluations, the possible certification activity of its customers.

Mazzucchelli has been producing, with proprietary formulas, Cellulose Acetate sheets since 1936 and has organized internally a structured and thorough method for the management and the evaluation of the substances and the collection of reports from the market.

Mazzucchelli has also carried out the tests required by the ISO 10993 standard on the two main formulations (Standard Plasticized Material DEP and M49) with positive results and has submitted the entire documentation to medical consultants working in hospitals who, in turn, have provided favorable opinions on biocompatibility.

The whole documentation, through which it was possible to achieve these positive results, has been collected in an organized way in a dossier named "*Profilo di sicurezza delle lastre di acetato di cellulosa Mazzucchelli*" and will be made available, upon request, to the Authorities responsible for any verification of compliance with **Regulation (EU) 2017/745**.

The Anfao Association, with the help of a consultant in charge of performing an audit, has examined the dossier and has acknowledged Mazzucchelli's correct approach by positively evaluating the reported evidences.

The results of the work done by Mazzucchelli are exclusively valid for Cellulose Acetate sheets produced by all the companies belonging to the Group.

The foregoing only refers to **Mazzucchelli products in the condition as supplied** and is guaranteed by the ability to properly select and monitor the components used. In this regard, we point out that the aesthetic (albeit similar) reproductions of our products formulated by Mazzucchelli's competitors do not necessarily imply the use of the same components and therefore might not be as safe and suitable for the use in Class I medical devices.

Mazzucchelli therefore guarantees that its products, on the basis of the tradition of use, the extensive literature collected and the tests carried out, **can be considered non-irritants and non-skin sensitising**. Nevertheless, it cannot be ruled out that **individual cases** of irritation or skin sensitisation due to one or more constituents used may occur.