



## **CLASSIFICATION OF FLUORESCEIN OPHTHALMIC STRIPS AS MEDICAL DEVICE POSITION PAPER OF THE EUROPEAN CONTACT LENS SOCIETY OF OPHTHALMOLOGISTS (ECLSO e.V.)**

Fluorescein ophthalmic strips have been used for many decades in Europe and the rest of World as a medical device. However, the Meddev guidance 2.1/3 Rev.3 describes fluorescein as an in-vivo diagnostic agent, and as such, considers that fluorescein strips should be re-classified as a medicinal product.

Should these devices become medicinal products, manufacturers would very likely stop their distribution in the European Union because of the extensive administrative procedures and the high costs related to EU marketing authorizations of drugs. Classifying fluorescein strips as medicinal product would therefore have a major impact on their availability. Fluorescein is not only used by ophthalmologists as a dye for diagnostic purposes and applanation tonometry but it is also mandatory to assess the fitting of rigid corneal and scleral contact lenses. These specialty lenses represent only a small segment of the market but they are most important for the visual rehabilitation of patients suffering from various conditions such as keratoconus, pellucid marginal degeneration and other severe irregularities of the cornea. Any shortage of fluorescein strips would have a negative impact on the rehabilitation of these visually impaired patients.

According to the Meddev guidance 2.1/3 Rev.3 it appears that solely the description as 'diagnosis' triggers the classification of fluorescein strips as a medicinal product and not any safety concerns. It must be stressed that fluorescein strips have been used as medical devices on millions of patients across Europe and the world in the past decades and that according to our search in the US National Library of Medicine no adverse events related to their topical use on the ocular surface have ever been reported. Furthermore, we consider that the fluorescein guided assessment of the proper fit of a contact lens on the surface of the eye is not as such a medical diagnosis.

The ECLSO supports therefore a more pragmatic approach using a dual classification system for fluorescein strips that would be available either as medicinal product for diagnostic purposes in accordance with Meddev guidance 2.1/3 Rev.3 or as medical device restricted to the visualisation and assessment of a contact lens fit on the cornea.

*The European Contact Lens Society of Ophthalmologists (ECLSO e.V) is a non-profit scientific organization of medical doctors based in Munich, Germany. The Society counts over 2000 members across Europe and is a major player in the field of contact lenses and ocular surface diseases.*

*For further information please contact: Dr. René Mély, ECLSO President, [mail@mely.org](mailto:mail@mely.org)*