



FLUORESCENT OPHTHALMIC STRIPS AND CONTACT LENS FITTING EUROPEAN CONTACT LENS FORUM (ECLF) position paper

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This paper intends to inform decision makers on the different capacities in which fluorescent ophthalmic strips are used. It **calls to include the non-diagnostic use of fluorescent ophthalmic strips in the Guidance Meddev 2.1/3 Rev.3, and to consider the product in this case to be a medical device.**

Introduction

Fluorescent ophthalmic strips are used for a wide variety of purposes by ophthalmologists, optometrists and opticians throughout Europe to colour the tears of the eye and pick up cell loss and tissue impact of contact lens wear. Fluorescent ophthalmic strips have been used this way for over 50 years without any adverse event reports. In the past and today still, in the majority of European countries fluorescent ophthalmic strips are considered a medical device, but it has recently been recognised that this is inconsistent with the EU legislation as clarified by the medical devices guidance document. The Meddev guidance 2.1/3 Rev.3 describes fluorescein as an in-vivo diagnostic agent, and as such, considers fluorescent ophthalmic strips to be a medicinal product. It appears that the description as 'diagnosis' triggers the classification as a medicinal product, however we would like to outline the negative impact this classification would have on the provision of eye care services throughout the region.

Diagnostic versus non-diagnostic use of Fluorescent ophthalmic strips:

a. Fluorescent ophthalmic strips used for diagnosis:

For some measurement techniques around the eye, done by eye care practitioners, such as in applanation tonometry, i.e. the measurement of intra-ocular pressure of the eye, the use of fluorescent ophthalmic strips is in combination with an anesthetic and assists in the diagnosis of ocular hypertension, and therefore should be seen as a medicinal product when used in this context .

However, there are many cases where the use of Fluorescent ophthalmic strips does not have a diagnostic purpose. Some uses are in the context of contact lens fitting as described below.

For both eye care practitioners and contact lens fitters, fluorescent ophthalmic strips are an aid to study the 'fit' of the lens, i.e. the areas where tears can accumulate under and around the contact lens. Contact lenses, especially rigid gas permeable ones (RGPs), come in different curvatures to best fit the shape of the cornea and ocular adnexa. This fit needs to be assessed, and if need be, altered. In some cases this shape is even customised to get the optimal fit for the individual wearer. The correct fit of the lens is important to ensure comfort and stability of vision with the contact lens. This is not a diagnostic procedure, but one which uses fluorescent ophthalmic strips to help visualise the fit of the contact lens and ensure the correct selection of contact lens shape.

The impact of classifying fluorescent ophthalmic strips used in contact lens fitting as a medicinal product

- Manufacturers stop the production of fluorescent ophthalmic strips because of the new and prohibitively high cost and different documentation requirements for registration as a medicinal product compared to the former conformity assessment procedure per the Medical Devices Directive. Contact lens fitters can no longer obtain fluorescent ophthalmic strips and therefore cannot fit the lenses anymore.
- Rigid lens manufacturers are typically SME's that will have to stop their activity because of decreasing demand. Fluorescent ophthalmic strips are essential for fitting such lenses, including keratoconus lenses, where the only alternative are scleral and mini scleral lenses, which also require 100% fluorescent ophthalmic strips imaging of the tears, as do Ortho-K rigid lenses.
- Both patients and consumers lose out as these lenses will no longer be available for their care and for many there will be no substitute providing the same quality of vision.

Possible consequences of non-availability of fluorescent ophthalmic strips:

- Small quantities of strips may be imported by eye care professionals directly from third world countries without CE marking and no authorized representation in the EU/EEA.
- Some professionals may take the risk of "self-made" fluorescent ophthalmic strips with potential impact on patient safety since these products would be manufactured without any quality control.

Conclusion: In contact lens fitting, fluorescent ophthalmic strips are used as a visualiser to colour the tears to make them visible under the blue light of the Slit or Buton lamp device. They are acting as a visualiser to observe the fit of a contact lens and the coverage of the tears.

According to Council directive 93/42/EEC, the definition of a medical device is *"any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

- diagnosis, prevention, monitoring, treatment or alleviation of disease,*

- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”

By this definition, for contact lens fitting, fluorescent ophthalmic strips should be regarded as a medical device, as they help to investigate the anatomy in order to fit the medical device contact lenses to the eye and do not achieve their principal intended action by pharmacological, immunological or metabolic means.

The Meddev Guidance 2.1/3 rev.3, page 10 states: “in-vivo diagnostic agents; e.g. fluorescent ophthalmic strips for diagnostic purposes” as an example of a medicinal product. However, the Meddev does not address non-diagnostic purposes. We propose to expand the Meddev to include fluorescent ophthalmic strips for non-diagnostic purposes as an example of a medical device.

Like for other products, the intended use of the product as defined by the manufacturer should determine the classification of the product as a medical device or as a medicinal product.

About ECLF, the author

The European Contact Lens Forum (ECLF) is the exchange platform between **all contact lens specialists and the contact lens / lens care industry**. It consists of (in alphabetical order):

- the European Contact Lens Society of Ophthalmology (ECLSO) www.eclso.eu
- the European Council of Optometry and Optics (ECOO) www.ecoo.info
- the European Federation of the Contact Lens Industry (EFCLIN) www.efclin.com
- the European Federation of National Associations and International Manufacturers of Contact Lens Products (EUROMCONTACT) www.euromcontact.org and
- the European representative of the International Association of Contact Lens Educators (IACLE). www.iacle.org

For further information, please contact

Anne-Marie Wolters, Secretary of the ECLF

c/o Euromcontact aisbl

Phone: +32 71 877 567

E-mail: info@eclf.eu

www.eclf.eu