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CLINICAL EVALUATION DOCUMENT ON CONTACT LENSES

Notified Bodies will start asking for clinical data now !

The 2007 revision of the European Medical Device Directive (2007/47/EC) introduced among many other changes, '... that clinical data is generally required for all devices, regardless of classification ...', as an essential requirement to be fulfilled for all classes of medical devices. The essential requirements must be met in order to put the CE mark on the product. The clinical data is usually based on data from clinical studies, which may not be available for some contact lenses that were first placed on the market many years ago and continuously supplied thereafter. One solution is here **to use published scientific articles to demonstrate fulfilment with this essential requirement**. From 2010 onward, Notified Bodies will be looking for these data in a greater degree of detail than would have been accepted in the past.

The EUROMCONTACT Regulatory Affairs Focus Group commissioned a **generic clinical evaluation document that manufacturers can use to help demonstrate compliance to the clinical requirements**. This literature review covers published literature on existing contact lens materials and modalities up to the present (2008) and focused mainly on peer reviewed articles. It contains over 400 references. It was developed by the internationally recognized experts Dr. Michael Port and Dr. Graeme Young (Vision Care Research – UK) who reviewed all the literature provided by EUROMCONTACT plus hundreds of published articles from various databases. It provides summaries of the safety and effectiveness of the different types of contact lenses on the market. It will **save you time and thousands of Euros by providing you with the first step toward meeting the essential requirements**.

Return this form by fax (+ 32 71 877 567 or e-mail – info@euromcontact.org)

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€ 1,200 for commercial organisations like Notified Bodies, consultants..

€ 1,200 for large companies not a member of the national CL associations

€ 1,000 for large companies members of the national CL associations

€ 500 for small companies members of the national CL associations (annual turnover <€2.5 million).

€ 600 for small companies not a member of the national CL associations.