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New regulatory documents available from Euromcontact

Clinical evaluation document: updates now available

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. The Ortho K package is now a part of the 2011 revision.

The Clinical Evaluation document is available at €875 for Lab Members, €1750 for supplier members and €2000 for any "non- members".

Updates to above Doc. €100 for Lab Members, €200 for supplier members and €250 "for non-members"

Risk Assessment Guidance document

The Medical Devices Directive requires that an appropriate risk assessment be undertaken and documented in the technical file. The Euromcontact document will provide you with the necessary guidance to develop your own file and gives many concrete examples.

The document can be purchased for € 60,- (for all EFCLIN members –lab and supplier) and € 100,- for non-members.

For all orders, please contact Anne-Marie Wolters, Secretary General of Euromcontact aisbl at info@euromcontact.org .