



CRITICAL HEALTH CERTIFIES RETMARKER SOFTWARE, A DECISION SUPPORT SOLUTION FOR OPHTHALMOLOGY

Retmarker has been qualified as a Medical Device in European market.

Coimbra, Portugal, 28th April, 2010 – Critical Health has announced that Retmarker, its software solution for decision support in the ophthalmology domain, attained the right to hold the “CE 0197” branding, that classifies it as a “Class IIa Medical Device” at a European level. This certification enables Critical Health to start commercializing this software tool, which allows for a detailed analysis, using non-invasive imaging methods, of several retinal pathologies. The attainment of this important milestone, which qualifies the company as a producer of Medical Devices, is supported on the certification of the company’s Quality Management System according to the “EN ISO 13485:2003 + AC:2007” and “EN ISO 9001:2008” standards.

“European legislation requires that the software used in this sector to be qualified as a Medical Device and hold the proper ‘CE’ branding. This branding guarantees the existence of evidences that the best development practices were applied, also guarantying that the risks and advantages for the patients and users were properly assessed. The Retmarker certification is an extremely important milestone for Critical Health, given that it enables us to start its commercialization and carry on with our ambitious business plan, which we have been following and that includes also setting up a global network of distributors”, underlines João Diogo Ramos, Business Unit Manager at Critical Health.

“Every test and trial that we have been conducting has confirmed the business potential associated with Retmarker. At this moment we are finalizing the process that will lead to the first Retmarker deployment in a commercial context”, states Ricardo Cunha-Vaz, the company’s CEO.

“The certification of the company as producer of Medical Devices, as outlined in the directive ‘93/42/EEC Annex II, Article 3, not only shows the commitment and the willpower that Critical Health puts into following European legislation, as it guarantees the quality of the groundbreaking technological solutions that the company has been developing in the areas of the prevention of loss of vision and mobility, putting Critical Health in the forefront of certification in this specific area of medicine, as well its concern regarding the patients’ wellbeing”, assures Paulo Santos, Commercial Director at Tüv Rheinland, the entity responsible for the certification.

Retmarker is a groundbreaking solution, recently distinguished in London with a European IT Excellence Award. Retmarker has been developed in conjunction with several experts from AIBILI (Association for Innovation and Biomedical Research on Light and Image), a R&D institute located in Coimbra. This system simplifies the diagnostic made by ophthalmologists, as they now have a more precise source of information, which is not prone to errors related to the complexity in the estimations of lesion areas present in each subfield of the retinography (colour fundus photograph).

Available in several versions, RetmarkerDR monitors the progression of Diabetic Retinopathy, using advanced proprietary algorithms that help ophthalmologists detect and calculate the formation and disappearance rates of microaneurysms in the retina and infer, with the help of this information, the evolution of a disease that is one of the highest growing causes of preventable blindness in developed countries. RetmarkerC enables the detection of changes in the retina due to several pathologies. As to RetmarkerAMD, it is a new solution in development that enables the computer-assisted marking of digital images of patients with Age-related Macular Degeneration (AMD), the main cause of blindness in persons over 50, in developed countries.

About Critical Health www.critical-health.com

Critical Health is a Critical Software spin-off and a holding of Critical SGPS, dedicated to the development of groundbreaking technological solutions in the field of loss of Vision and Mobility prevention. One solution developed by Critical Health is Retmarker, a decision support tool available in different versions, developed to detect and monitor ophthalmological lesions. Other groundbreaking solution is the Health Monitoring solution, a system for remote monitoring that enable better healthcare services for elderly persons in assisted living facilities. Critical Health’s innovative solutions are developed through partnerships with the best Universities, Hospitals and Scientific Research Institutions.

###