

Press release

Diagnoptics receives Chinese market approval for AGE Reader SU.

Groningen, the Netherlands – February 12, 2016.

Diagnoptics has received market approval from the Chinese Food and Drug Administration (CFDA) for the AGE Reader SU. This allows the Chinese distributor of the AGE Reader, Costrength Science&Technology Development Co, LTD., to market the AGE Reader SU in China.

This approval means entry to one of the major markets for the AGE Reader SU. Chinese healthcare professionals are now allowed to use the AGE Reader SU. Bart van den Berg, CEO of Diagnoptics, said: “Securing market approval in China is a significant milestone accomplishment for the Diagnoptics team and our Chinese distribution partner, Costrength. China is one of the largest potential markets in the world for point-of-care diagnostics. This represents a vast opportunity for Diagnoptics and Costrength.”

After extensive tests, the CFDA approved the marketing of the AGE Reader in China to measure tissue accumulation of Advanced Glycation Endproducts (AGEs) by means of fluorescence techniques (skin autofluorescence). AGEs are known to play a key role in the pathogenesis of many age-related diseases, such as diabetes, cardiovascular disease and renal failure. The AGE Reader has been proven in clinical studies to provide an immediate cardiovascular risk prediction for major chronic diseases, such as diabetes, cardiovascular disease and renal failure. The method is convenient, easy to use and validated in many international studies.

Diagnoptics was the first company worldwide to introduce a technology to non-invasively measure the tissue accumulation of AGEs by means of fluorescence techniques (AGE Reader). The AGE Reader has been used in clinical practice and research since 2006. Since the introduction of the AGE Reader over 150 peer reviewed scientific papers have been published. By now thousands of healthcare professionals use the AGE Reader every day.

About Diagnoptics

Established in 2003, Diagnoptics is the pioneer and inventor of cutting edge diagnostic devices that can non-invasively diagnose and assess the risk of diabetes and its complications. Its technological advance in detecting fluorescence of Advanced Glycation Endproducts (AGEs) has led to the invention of the AGE Reader - a state of art diagnostic device that can non-invasively determine the tissue accumulation of AGEs. Since the CE certification on the first AGE Reader in 2006, Diagnoptics has been marketing this medical device to thousands of clinics around the world. Currently the company is working on obtaining additional regulatory approvals in other regions and is engaged in new product development activities. The head office of Diagnoptics Technologies BV is in Groningen, the Netherlands.

About AGE Reader

The AGE Reader provides an immediate cardiovascular risk prediction for major chronic diseases, such as diabetes, cardiovascular disease and renal failure. The AGE Reader yields a real time and non-invasive assessment of cardiovascular risk. The method is convenient, easy to use and validated. The AGE Reader measures tissue accumulation of Advanced Glycation Endproducts (AGEs) by means of fluorescence techniques (skin autofluorescence). AGEs play a key role in the pathogenesis of many age-related diseases, such as diabetes, cardiovascular disease and renal failure. Since the market introduction in 2006, the AGE Reader has been clinical validated extensively in over 140 peer reviewed scientific publications.

AGEs are essential biomarkers of metabolic and glycemic stress and have been implicated as causative factors in the progression of a host of age-related diseases, such as atherosclerosis, diabetes, renal failure and Alzheimer. The level of AGEs in tissue reflects the glycometabolic memory and is a valuable predictor of (pre)diabetes and cardiovascular complications.

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