

Press release

DiagnOptics receives ISO 13485 certification.

Groningen, the Netherlands – June 1, 2010

DiagnOptics has received ISO 13485 certification for the design, development, manufacture, sales and support of the AGE Reader.

The Dutch Groningen based medical technology company DiagnOptics announces that it has received the ISO 13485 certificate. ISO 13485 is the equivalent of ISO 9001 for manufacturers of medical devices. ISO 13485 verifies that a medical device manufacturer complies with the appropriate regulatory quality system requirements and it assumes that the manufacturer has the appropriate controls in place to ensure that the device developed and manufactured can be considered safe and effective.

Together with the CE certification, this certification enables DiagnOptics to achieve regulatory approval of the AGE Reader in countries outside the European Union. DiagnOptics' managing director Bart van den Berg: 'We are very pleased with obtaining the ISO 13485 certification. This certification gives us to opportunity to expand the marketing of the AGE Reader to important markets like the USA, China, Canada and Russia.'

About DiagnOptics

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 determine the tissue accumulation of AGEs in 30 seconds. Since the CE certification on the first AGE Reader in 2006, DiagnOptics has been marketing this medical device to hundreds of clinics around the world and it introduced the all-in-one AGE Reader CU at the end of 2009. 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. [Read more.](#)

About AGE Reader

The AGE Reader provides an immediate 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. [Read more.](#)

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