

Liège, Belgium, January 20th, 2009.



Eurogentec recently received ISO 13485:2003 certification for the production and sales of *In Vitro* Diagnostic (IVD) oligonucleotides. ISO 13485 is recognized as the global standard for quality management systems relating to the design, development, production, installation and servicing of medical devices. Eurogentec undertook this rigorous medical device quality system certification as part of its increasing commitment to the molecular diagnostic markets. Eurogentec has been certified to the ISO 9001 standard since 2000.

Over the past five years, Eurogentec has supplied oligonucleotides to Molecular Diagnostic companies and CLIA-certified clinical labs. The ISO 13485 certification provides added assurance to our clients that Eurogentec has established highly reliable, effective and reproducible processes for manufacturing of oligonucleotides used in molecular diagnostic devices and Lab Developed Tests (LDTs). It also confirms our compliance with the European IVD directive 98/79 EEC and U.S. FDA regulations for Good Manufacturing Practices (21 CFR Part 820 QSR/cGMP) and Analyte Specific Reagents (21 CFR Part 820, 21 CFR 809.10, 809.30, 864.4020).

“ISO 13485 certification is another important milestone in Eurogentec’ s strategy to further grow our presence in the rapidly growing North American and European molecular diagnostics markets,” says Dr. Peter Haima, Global Manager IVD services. “In 2008 we opened a new world class GMP clean room oligonucleotide manufacturing facility in Belgium and a new GMP-capable oligonucleotide manufacturing facility at our North American headquarters in San Diego, California. We also hired a new General Manager, Ms. Diane Wolfe, to head our North American operations. Ms. Wolfe brings 18+ years of experience in the molecular diagnostic industry. With these important milestones completed, we are now preparing for ISO 13485 certification of our San Diego Facility and the launch of new and exciting diagnostic services for the North American market.”

About Eurogentec

From its global headquarters in Liège, Belgium, Eurogentec has been a leading provider of innovative products and services to the Life Science, Diagnostic and Pharmaceutical communities for over 20 years. The company has distribution networks in over 40 countries and employs more than 350 people worldwide. The main cGMP oligonucleotide production site in Belgium is complemented by additional production facilities in the USA, Japan and Singapore providing B2B customers with redundant capabilities and harmonized methods, procedures and Quality Management Systems. In addition to GMP diagnostic oligonucleotide production, the parent company operates an authorized facility for the GMP manufacturing of biologics.

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