



GENOMICS | DIAGNOSTIC TESTS | GENETICS | R&D

GENOMIC VISION OBTAINS NF EN ISO 13485:2012 QUALITY CERTIFICATION

Bagneux, France - Genomic Vision (FR0011799907 – GV), a molecular diagnostics company specializing in the development of diagnostic tests for genetic diseases and cancers based on molecular combing technology, announces that it has obtained NF EN ISO 13485:2012 quality assurance certification for its manufacturing, sales and related services (installation, maintenance) activities relating to in vitro diagnostic instruments and kits used in molecular genetic testing for human pathologies.

NF EN ISO 13485:2012 is an international quality assurance standard that ensures the implementation of regulatory requirements applicable to medical devices and related services. This certification was granted by the LNE-GMED, the reference body for certification in the field of medical diagnostics.

“Obtaining this certification confirms our intention of putting client satisfaction at the centre of our concerns by providing high-quality state-of-the-art products. Continual improvement at the heart of the Quality Management System’s performance will enable us to provide increasingly sophisticated and efficient DNA-analysis solutions”, says Aaron Bensimon, Genomic Vision’s co-founder and Chairman.

ABOUT GENOMIC VISION

Founded in 2004, Genomic Vision is a molecular diagnostics company that specializes in the development of diagnostic tests for genetic diseases and cancers based on molecular combing. Using this innovative technology that allows the direct visualization of individual DNA molecules, Genomic Vision detects quantitative and qualitative variations in the genome that are at the origin of numerous serious pathologies. The Company is developing a solid portfolio of tests that initially target breast and colon cancers. Since 2013, the Company has marketed the CombHelix FSHD test for identifying facioscapulohumeral dystrophy (FSHD), a myopathy that is difficult to detect. It is marketed in the United States through a strategic alliance with Quest Diagnostics, the American leader in diagnostic laboratory tests, and in France directly by the Company. Genomic Vision has been listed on Compartment C of Euronext Paris since April 2014.

ABOUT MOLECULAR COMBING

DNA molecular combing technology significantly improves the structural and functional analysis of DNA molecules. DNA fibers are stretched over glass slides, as if "combed", and uniformly aligned over the entire surface. It is then possible to identify genetic anomalies by locating specific genes or sequences in the patient's genome using genetic markers, a technique developed by Genomic Vision and patented under the name Genomic Morse Code. This exploration of the entire genome at high resolution via a simple analysis enables the direct visualization of genetic anomalies that are undetectable by other technologies.

For further information, please go to: www.genomicvision.com

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