



GENOMICS | GENETICS | R&D | DIAGNOSTIC TESTS

Genomic Vision obtains the renewal of the ISO 13485: 2016 certification

Bagneux (France) – GENOMIC VISION (FR0011799907 – GV). Within the compliance cycle of Standard NF EN ISO 13485 by the subsidiary GMED (LNE Group), an independent notified body empowered by the French National Agency for Medicines and Health Products Safety (ANSM) for the conformity assessment of in vitro diagnostic medical devices according to Regulation (EU) 2017/746, Genomic Vision received the decision for the renewal of its certificate.

The renewal of this certification since 2016 confirms that Genomic Vision's quality management system continues to meet the specific standards required for the Design, manufacturing, sale and associated servicing (installation and maintenance) of in vitro diagnostic instruments and kits used for the molecular genetic diagnosis of human pathologies.

Mohamed-Salah Garouachi, Quality & Regulatory Affairs Director of Genomic Vision, said: *"The renewal of our certification since 2016 confirms our ability to meet regulatory and quality requirements necessary to bring our in vitro diagnostic medical devices to market. Indeed, the ISO 13485:2016 standard can serve as a common basis to address regulations in different regions like North America."*

The internationally recognized ISO 13485 standard is the reference for the implementation of a quality management system when an organization needs to demonstrate its ability to continually provide medical devices and associated services that meet customer and applicable regulatory requirements.

Dominique Remy-Renou, CEO of Genomic Vision, added: *"This certification applies only to our In vitro diagnostic products (IVD-MD). However, we apply the same level of requirements to all our products, reflecting our commitment to customer satisfaction."*

ABOUT GENOMIC VISION

GENOMIC VISION is a biotechnology company developing products and services dedicated to the analysis (structural and functional) of genome modifications as well as to the quality and safety control of these modifications, in particular in genome editing technologies and biomanufacturing processes. Genomic Vision proprietary tools, based on DNA combing technology and artificial intelligence, provide robust quantitative measurements needed to high confidence characterization of DNA alteration in the genome. These tools are mainly used for monitoring DNA replication in cancerous cell, for early cancer detection and the diagnosis of genetic diseases. Genomic Vision, based near Paris in Bagneux, is a public listed company listed in compartment C of Euronext's regulated market in Paris (Euronext: GV – ISIN: FR0011799907).

For further information, please visit www.genomicvision.com

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