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Press release for immediate release

Genomtec receives ISO 13485 certification completing another essential step in the Genomtec ID project

Wroclaw, Poland – August 6, 2021 - Genomtec SA, listed on the NewConnect market at Warsaw Stock Exchange, a company developing medical technology applicable in the segment of clinical diagnostics at the point of care testing – POCT, has been certified in accordance to ISO 13485 standard for its quality management system compliance via audits carried out by TÜV Rheinland - a prestigious, independent Certification Body. The certificate was awarded for the design and development of IVD devices for the detection of pre-determined pathogens and confirms Company's top commitment towards quality development of medical devices. Obtained certification is necessary for the purpose of Genomtec ID mobile genetic diagnostic platform registration that is planned for mid-2022.

In August 2020, a second certification audit took place at the Company by the TÜV Rheinland Certification Body and since then the Company has been waiting for its to be issued. The granted certificate expirers on November 2023.

The ISO 13485 standard is an effective tool informing of the comprehensive Quality Management System use in the area of medical devices. The adoption of ISO 13485 standard provides Genomtec with a practical work-frame being implemented in accordance to the Medical Device Directives and other regulations and obligations. It also confirms Company's commitment towards the safety and quality of manufactured medical devices. Moreover, it increases the market opportunity of the Company's flagship project, i.e. Genomtec ID, simultaneously being a crucial element of its industrialization the process.

- The ISO 13485 certificate is yet another very important step towards commercialization of Genomtec ID. We have confirmed that our quality management system is compliant with the highest global standards. Conformance to the standard gives us a competitive product advantage and will certainly facilitate access to the foreign markets. Our future customers received confirmation that the Genomtec ID mobile genetic diagnostic platform will be made with an adequate diligence and that the product it is completely safe to use. The entire team has worked extremly hard to achieve this top level of quality. We want to continue our development, raising the standards-bar high - said Miron Tokarski, Co-founder and President of Genomtec.

The certificate was awarded by TÜV Rheinland - a market-leading Certification Body in the field of design and development standards compliance in Europe. The company is part of the TÜV Rheinland Group, a leading international conglomerate providing services to the industry worldwide. ISO 13485

is a standalone Quality Management System standard for medical devices and IVD products derived from the family of internationally recognized and accepted ISO 9000 quality management standards. It is much more detailed and requires a carefully documented Quality Management System operations in place.

ISO 13485 standard was written to support medical device manufacturers in developing and sustaining quality management systems that provide their processes' effectiveness. This standard ensures the consistent design, development, manufacturing, installation, and delivery of medical devices that are safe for their intended use.

Genomtec's flagship solution - the Genomtec ID is a mobile diagnostic platform employing microfluidic system and the proprietary, patented SNAAT® technology. This innovative diagnostic system will be able to carry out several tests from one sample simultaneously, including causal determination of respiratory tract infections or sexually transmitted diseases, even in 15 minutes. Genomtec ID will be used for point of care diagnostics, i.e., in doctor's offices, emergency department, and even a pharmacy. The commercialization of the platform is planned for mid-2022.

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Additional information available at:

Genomtec S.A.
Magdalena Kicińska
+48 604 201 230
m.kicinska@genomtec.com

About Genomtec S.A.

Genomtec is an innovative medical technology company dedicated to the development and commercialization of a mobile molecular diagnostics platform for detection of various infectious diseases, and also rapid laboratory diagnostic tests used, among others, in the detection of COVID-19 disease caused by the SARS-CoV-2 virus.

The company's flagship project is the Genomtec ID mobile IVD platform. The analyser is uniquely placed among Point-Of-Care (POC) products worldwide. It will allow for a quick and precise clinical molecular analysis outside the standard laboratory setting, without the need to involve qualified laboratory personnel. The system uses microfluidic technology and the proprietary, patent protected SNAAT® isothermal technology. Appropriate design of the system enables the process to be carried out in record time, i.e. even in 15 minutes, with the diagnostic parameters equal to, and in some cases exceeding, the quality of PCR laboratory tests.

The development and manufacturing process is executed in close cooperation with international CMO (Contract Manufacturing Organization) companies. According to the assumptions of the Genomtec Management Board, the commercialization of the flagship solution will take place in the first half of 2022.

Manufacturing of Genomtec® SARS-CoV-2 EvaGreen® laboratory tests in RT-LAMP technology is based in Poland, with current EU market authorisation (CE-IVD), and product registration started in other regulatory jurisdictions outside Europe.

Genomtec was founded in 2016. Genomtec SA is headquartered in Wroclaw.

More information at: www.genomtec.com