Wrocław, 08/06/2021

Current Report No 18

TÜV Rheinland has issued ISO 13485 certificate for Genomtec

Management Board of Genomtec S.A. ("the Issuer") hereby announces that as of today, i.e. on 6th Aug 2021, has been awarded by TÜV Rheinland the standard ISO 13485 certificate.

TÜV Rheinland is a leading certification body in the European certification and research services segment. The company is part of the TÜV Rheinland Group, an international blue-chip conglomerate providing services to the industry worldwide.

The certificate was issued for the design and development of the in-vitro diagnostic systems.

The Company underwent the second certification audit by TÜV Rheinland certification body in August 2020 and since then the Company has been waiting for the above certificate to be issued. The certificate is valid until November 2023.

Obtaining the certificate that confirms Company's conformance to and proper implementation of a quality management system is an important step towards registration of the Genomtec ID diagnostic platform.

The ISO 13485 standard is an efficient solution to meet the comprehensive requirements of the Quality Management System. The adoption of the ISO 13485 standard provides the Issuer practical means of implementation of the directives on medical devices, regulations and obligations, and also ensures its commitment to the safety and quality of manufactured medical devices. Having certification increases overall performance, manages risks, and increases market opportunities.

Obtained certification confirms commercial maturation of the Company's flagship solution and is an important element in the industrialization stage.

Therefore, in the opinion of the Management Board, this information meets the criteria of confidential information within the meaning of Art. 7 sec. 1 MAR.