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Market authorisation for sales of Genomtec® SARS-CoV-2 EvaGreen® Direct-RT-LAMP CE-IVD Kit

The Management Board of Genomtec S.A. („Company", „Issuer") registered in Wroclaw, Poland, hereby informs that after expiry of the legislative deadline prerequisite when registering a new medical device for in-vitro diagnostic at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Genomtec® SARS-Cov-2 EvaGreen® Direct-RT-LAMP CE-IVD Kit diagnostic test has been granted full market authorisation for sales in the European Union.

The new product of the Issuer is a CE-IVD laboratory kit constituting of assay controls and reagents for streamlined isolation, reverse transcription and amplification of nucleic acid utilizing the Reverse Transcription Loop-Medicated Isothermal Amplification (RT-LAMP) reaction for SARS-CoV-2 virus detection. The product, while maintaining the high level of diagnostic parameters, exhibits additional two very distinguishable and important features.

Firstly, it enables biological material collection in a form of a native saliva sample, which is a non-invasive method for the patient, as oppose to throat or nasopharyngeal swab collection, and does not require presence of a specialist personnel, simultaneously reducing personnel's exposure to virus contraction.

Secondly, utilization of a special buffer prevents conducting a full genetic material isolation from a sample in this test, which decreases the time needed to perform the entire diagnostic procedure by almost 60% and significantly lowers the cost of the entire diagnostic process.

The development of new products in the field of in-vitro diagnostics is one of the key elements of the Issuer's strategy, thereby confirming its competency and high level of know-how. The commercial launch of a new product may also have a significant impact on the Issuer's economic activity and generated revenue. For these reasons, in the opinion of the Management Board, this information meets the criteria of confidential information within the meaning of Art. 7 sec. 1 MAR.