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ASX Announcement

TBG Biotechnology Xiamen Inc. Confirms CE Mark Approval of SARS-CoV-2 Antigen Rapid Test

TBG Diagnostics Limited (“Company”) announces that its investee company TBG Biotechnology Xiamen Inc. (“TBG Xiamen”), a China based molecular diagnostics company, has received the CE Mark approval for its SARS-CoV-2 Antigen Rapid Test.

CE-Mark certification indicates that the SARS-CoV-2 Antigen Rapid Test meets the essential requirements of all the applicable European regulations and allows for its sale throughout the European Economic Area as well as any country that accepts CE-mark, subject to satisfying regulatory requirements and obtaining import permits for individuals countries. This antigen rapid test kit is manufactured by TBG Xiamen in China and will be exported from China.

SARS-CoV-2 Antigen Rapid Test is a lateral flow assay that is able to detect the presence of SARS-CoV-2 (COVID-19) virus in human throat swab and nasal swab samples.

The Company has a 46.65% ownership interest in TBG Biotechnology Xiamen.

CE Mark approval was granted on 30 October 2020 and confirmation of the CE Mark approval was received by TBG Xiamen on 10 November 2020.

Authorised by:

Jitto Arulampalam
Executive Chairman
On behalf of the Board of Directors
TBG Diagnostics Limited

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