# 杭州啓明醫療器械股份有限公司
# Venus Medtech (Hangzhou) Inc.

*(A joint stock company incorporated in the People's Republic of China with limited liability)*

**(Stock Code: 2500)**

## VOLUNTARY ANNOUNCEMENT
## VENUSP-VALVE OBTAINS CE MARKING UNDER MDR

This announcement is made by Venus Medtech (Hangzhou) Inc. (the "**Company**") on a voluntary basis. The board of directors of the Company (the "**Board**") is pleased to announce that on April 8, 2022, VenusP-Valve, the Company's in-house developed innovative transcatheter pulmonic valve replacement (TPVR) system, received CE marking under the Medical Devices Regulation (CE MDR) and marketed in Europe. Designed to treat patients with moderate to severe pulmonic regurgitation with or without right ventricular outflow tract stenosis, VenusP-Valve is the first self-expanding TPVR product approved for market in Europe, which is also the first Class III implantable cardiovascular device approved under CE MDR.

Moderate to severe pulmonic regurgitation is common after surgical correction of congenital heart disease. It leads to right ventricular volume overload and may cause arrhythmia and even sudden death in the long run. The traditional thoracotomy approach to pulmonic valve replacement is difficult and carries high mortality, while existing TPVR products in the European market, due to their balloon-expandable design, apply to patients with particular anatomic structures only and require pre-stenting. Moreover, as these valves come in small diameters, they only work for 15% to 20% of patients. There was no TPVR product suitable for different anatomical structures and available in such a wide range of specifications.

Uniquely designed with both flared ends, the product provides stable anchoring and easy delivery, with no need for pre-stenting before the procedure. Available in a variety of specifications with extensive applicability, the product is able to meet the needs of 85% of patients. Following its first clinical implantation in 2013 by Academician Ge Junbo, Director of Cardiology at Zhongshan Hospital, Fudan University, VenusP-Valve has been used for 9 years, in nearly 300 cases for humanitarian reasons, spanning more than 20 countries and regions in Asia, Europe, North America, and South America. In March 22, 2021, VenusP-Valve received special use authorization from the United Kingdom Medicines and Healthcare products Regulatory Agency for use in designated medical institutions.

According to two-year follow-up interim result of the clinical study on VenusP-Valve in Europe, the product demonstrated 100% procedural success, with no reoperation or death observed in two years. In addition, moderate pulmonic regurgitation decreased from 16.88% preoperatively to 0%, and severe pulmonic regurgitation plunged from 83.12% to 1.54%. The data suggests excellent performance, robust safety and reliability, and drastic and steady improvements in patients' cardiac function.

As published on the official website of European Union, there was no Class III implantable cardiovascular device approved since MDR came into effect in May 2021 in Europe. MDR taking place of the previous Medical Devices Directive, set out stricter and more specific standards in technical review and clinical evaluation and require the establishment of Expert Panels to support such evaluations. The approval of VenusP-Valve demonstrates the innovation of the product and high standard of clinical trial and quality control systems.

The Board believes that the launch of VenusP-Valve in Europe is a major milestone of the company's commercialization in overseas markets and marks the overall acceleration of the internationalization. Meanwhile, the approval of the CE MDR in Europe will also help promote the approval of VenusP-Valve around the world benefiting more clinical patients. Apart from Europe, VenusP-Valve is undergoing review and approval of registration with the Chinese National Medical Products Administration and is expected to be marketed within 2022. With plans to launch clinical trials in the United States in 2023, Venus Medtech is preparing for its investigational device exemption application to the Food and Drug Administration.

By order of the Board
**Venus Medtech (Hangzhou) Inc.**
**Min Frank Zeng**
*Chairman*

Hangzhou, April 11, 2022

*As at the date of this announcement, the executive Directors are Mr. Min Frank Zeng, Mr. Zhenjun Zi and Mr. Lim Hou-Sen (Lin Haosheng); the non-executive Director is Ms. Nisa Bernice Wing-Yu Leung; and the independent non-executive Directors are Mr. Ting Yuk Anthony Wu, Mr. Wan Yee Joseph Lau and Mr. Chi Wai Suen.*