By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Guangzhou Pluslife Biotech Co., Ltd.
Room 402
No. 6 Lianhuayan Road
Huangpu District
Guangzhou
Guangdong
510700
China

广州普世君安生物科技有限公司
中国
广东省
广州市
黄埔区
莲花砚路6号
402
邮编：510700

Holds Certificate No: **MD 748304**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of in vitro diagnostic nucleic acid detection kits and fluorescence detectors based on thermostatic amplification for diagnosis of infectious diseases. Design, development, manufacture and distribution of protein components used in in vitro diagnostic reagent.
用于传染病检测的，且基于恒温扩增荧光技术的体外诊断核酸检测试剂盒和检测仪的设计、开发、制造和分销。用于体外诊断试剂中的蛋白类组分的设计、开发、制造和分销。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-09-18
Latest Revision Date: 2021-09-18

Effective Date: 2021-09-18
Expiry Date: 2024-09-17

...making excellence a habit.™

Declaration of Conformity

MANUFACTURER:	Guangzhou Pluslife Biotech Co., Ltd. Room 402, 6 Lianhuayan Road, Huangpu District, Guangzhou, Guangdong, China Tel: +86-20-84156831 E-Mail: corporation@pluslife.com
PRODUCT INFORMATION:	Product Name: FHV-1/C.felis/M.felis Nucleic Acid Test Card Trade Name: Pluslife FCM Card Cat. No.: RM2010100-1, RM2010100-2, RM2010100-5, RM2010100-10, RM2010100-20, RM2010100-50

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above is/are defined as low risk and meet/s the essential requirements and other relevant requirements of the following Directives, Guidelines and Laws:

Directive 85/374/EEC on product liability;
Directive 2001/95/EC on general product safety;
Good Manufacturing Practice (GMP);
German Animal Health Act.

Signature:	Nook Chen
Title:	General Manager
Date:	*Sept.8, 2022*
Place:	Guangzhou, P.R. China