



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Research and Development Division,

> Eternal Materials Co., Ltd. No. 22, Changxing Rd.,

Luzhu Dist. Kaohsiung City

82150 **Taiwan**

Holds Certificate No: MD 698193

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

> The design, manufacturing and sales of enzymes used for molecular and biochemical in vitro diagnostic devices.

The design, manufacturing and sales of rapid test kits for Dengue virus.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Gary C Stade

Original Registration Date: 2019-02-19 Latest Revision Date: 2019-12-17

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...making excellence a habit."

Effective Date: 2019-02-19

Expiry Date: 2022-02-18

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract, An electronic certificate can be authenticated online. Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +886 (02)2656-0333.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.