

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Eternal Materials Co., Ltd. Luzhu plant
No. 22, Changxing Rd.
Luzhu Dist.
Kaohsiung City
82150
Taiwan

Holds Certificate Number:

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 and antigens for the diagnosis of infectious diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-02-19

Latest Revision Date: 2024-12-02

Effective Date: 2025-02-19

Expiry Date: 2028-02-18

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Eternal Materials Co., Ltd.

31F-6, 31F-1, 31F-10
No. 99, Sec. 1, Xintai 5th Rd.
Xizhi Dist.
New Taipei City
221
Taiwan

Holds Certificate Number:

MD 757242

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

The design, manufacture and sales of rapid test kits using immunochemistry technology for detection of the infection disease.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-02-17

Effective Date: 2025-02-17

Latest Revision Date: 2024-12-20

Expiry Date: 2028-02-16

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