

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Helaxy Pte Ltd**  
16 Ayer Rajah Crescent #03-02  
Tempco Technominium  
139965  
Singapore

Holds Certificate Number: MD 778370

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

Design and development, manufacture and distribution of in-vitro diagnostic reagents used in the detection and disease management of infectious diseases, cancer markers, genetic diseases and metabolic diseases.

Design and development, manufacture, distribution, installation and service of in-vitro diagnostic instruments and software used in the detection and disease management of infectious diseases, cancer markers, genetic diseases and metabolic diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-03-01

Latest Revision Date: 2024-04-11

Effective Date: 2023-03-01

Expiry Date: 2026-02-28

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