bsi.

By Royal Charter

Certificate of Registration

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

This is to certify that:

Seegene Inc.
Taewon Bldg.,
91, Ogeum-ro,
Songpa-gu,
Seoul
05548
Republic of Korea

Holds Certificate Number: MD 554228

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, development, manufacture, packaging, storage, servicing and distribution of in vitro diagnostic reagents, kits and software, instruments and accessories for the detection of infectious disease by molecular diagnostics.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2009-09-18
Latest Revision Date: 2024-09-29

Effective Date: 2024-10-13
Expiry Date: 2027-10-12

...making excellence a habit.™

UKAS MANAGEMENT SYSTEMS 0003

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.bsigroup.com/ClientDirectory

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.