

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

SAGA Diagnostics AB
Scheelevagen 2,
MV406,
223 81 Lund,
Sweden

Holds Certificate Number:

MD 750388

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

Design, development, manufacturing and distribution of in vitro diagnostic medical devices using nucleic acid analysis intended for molecular biological testing to aid in the evaluation of cancer.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-03-11

Latest Revision Date: 2022-03-11

Effective Date: 2022-03-11

Expiry Date: 2025-03-10

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