

Certificate of Registration

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

This is to certify that:

Rossix AB
Taljegardgatan 3B
43153 Molndal
Sweden

Holds Certificate Number:

MD 649316

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 and sales of in-vitro diagnostic reagents and kits for the diagnosis of coagulation disorders.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-02-08

Latest Revision Date: 2020-01-27

Effective Date: 2020-02-08

Expiry Date: 2023-02-07

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