



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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-02-08

Latest Revision Date: 2023-01-19

Effective Date: 2023-02-08 Expiry Date: 2026-02-07

Page: 1 of 1

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...making excellence a habit."

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 <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory