



Certificate of Registration

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

This is to certify that:

Boule Medical AB Domnarvsgatan 4, SE-163 53 Spånga Sweden

Holds Certificate Number:

MD 717615

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

The development, manufacturing, marketing, servicing, installation and distribution of laboratory systems for clinical diagnostics.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-09-24 Latest Revision Date: 2022-05-11 Effective Date: 2022-05-21 Expiry Date: 2025-05-20

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...making excellence a habit."

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Information and Contact: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780 BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Certificate No: MD 717615

Location

Boule Medical AB Domnarvsgatan 4, SE-163 53 Spånga Sweden

Boule Medical AB Fagerstagatan 7, SE-163 53 Spånga, Sweden **Registered Activities**

The development, manufacturing, marketing, servicing, installation and distribution of laboratory systems for clinical diagnostics.

The manufacturing of laboratory systems for clinical diagnostics.



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