

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, manufacture, servicing, installation and distribution of laboratory systems for clinical diagnostics.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-09-24

Latest Revision Date: 2025-03-31

Effective Date: 2025-05-21

Expiry Date: 2028-05-20

Page: 1 of 2



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Certificate No: MD 717615

Location	Registered Activities
Boule Medical AB Domnarvsgatan 4, SE-163 53 Spånga Sweden	The development, manufacture, servicing, installation and distribution of laboratory systems for clinical diagnostics.
Boule Medical AB Fagerstagatan 7, SE-163 53 Spånga, Sweden	The manufacture of laboratory systems for clinical diagnostics.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
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