

Certificate of Registration

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

This is to certify that: **Boule Medical AB**
Fagerstagatan 7,
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:

Design, development, manufacture, installation, service and distribution of hematology analysers, calibrators, controls and reagents for clinical diagnosis.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-09-24

Latest Revision Date: 2026-04-07

Effective Date: 2025-05-21

Expiry Date: 2028-05-20

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