

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

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

Holds Certificate Number:

MD 629116

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

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

For and on behalf of BSI:



Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 10/03/2015

Latest Revision Date: 17/05/2016

Effective Date: 21/05/2016

Expiry Date: 28/02/2019

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Certificate No: MD 629116

Location

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

Registered Activities

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

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

The manufacturing of laboratory systems for clinical diagnostics.



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