

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - EN ISO 13485:2016

This is to certify that:

**BluSense Diagnostics Aps.**

Fruebjergvej 3  
Copenhagen Ø  
2100  
Denmark

Holds Certificate Number:

MD 663350

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

Design, development, manufacture and distribution of IVD analysers and reagents for detection of biomarkers to diagnose diseases

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-06-22

Latest Revision Date: 2017-06-22

Effective Date: 2017-06-22

Expiry Date: 2020-06-21

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