

# Certificate of Registration

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

This is to certify that:

Fluisense ApS  
Gydevang 20A  
DK 3450 Allerød  
Denmark

Holds Certificate Number:

**MD 674969**

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

Design and development, manufacture and distribution of medical devices for blood sampling, including catheters, sterile blood collection cartridges, control unit and software. Contract assembly of sterile blood contacting catheters.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-12-01

Latest Revision Date: 2021-12-01

Effective Date: 2021-12-01

Expiry Date: 2024-11-30



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