



## Certificate of Registration

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

This is to certify that:

Arctic Biomaterials Oy Arvo Ylpön katu 41 Tampere 33520 Finland

Holds Certificate Number:

MD 636892

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

Design, manufacture and primary packaging of non-sterile polymer composite material products for implantable medical devices and polymer composite material testing services

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-02-24 Latest Revision Date: 2022-02-15

bsi.



Effective Date: 2022-02-24 Expiry Date: 2025-02-23

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...making excellence a habit."

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

## Certificate No: MD 636892

Location

Arctic Biomaterials Oy Arvo Ylpön katu 41 Tampere 33520 Finland

Arctic Biomaterials Oy Telinetie 5 A 3 Lempäälä 33880 Finland **Registered Activities** 

Design, manufacture and primary packaging of non-sterile polymer composite material products for implantable medical devices and polymer composite material testing services

Manufacture of Glass Fiber material



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