



## Certificate of Registration

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

This is to certify that:

BellaSeno GmbH Deutscher Platz 5a Leipzig 04103 Germany

Holds Certificate Number:

MD 701726

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 additive manufacture of sterile absorbable porous implantable breast scaffolds, sterile custom-made absorbable porous implantable pectus scaffolds and sterile custom-made absorbable porous implantable bone scaffolds.

Contract manufacture of additively manufactured sterile absorbable porous implantable breast scaffolds, sterile absorbable porous implantable pectus scaffolds and sterile absorbable porous implantable bone scaffolds.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-07-01 Latest Revision Date: 2023-03-29 Effective Date: 2022-07-01 Expiry Date: 2025-06-30

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780 BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.