

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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