

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.
Contract manufacture of additively manufactured implants.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-07-01

Latest Revision Date: 2022-06-21

Effective Date: 2022-07-01

Expiry Date: 2025-06-30

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