

# 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:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-07-01

Latest Revision Date: 2019-07-01

Effective Date: 2019-07-01

Expiry Date: 2022-06-30

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Certificate No: **MD 701726**

Location

BellaSeno GmbH  
Deutscher Platz 5a  
Leipzig  
04103  
Germany

Registered Activities

Design of sterile porous implantable scaffolds.

Fraunhofer Institute for Cell Therapy  
and Immunology  
Perlickstrasse 1  
Leipzig  
04103  
Germany

Additive manufacture of sterile absorbable porous  
implantable breast scaffolds.  
Contract manufacture of additively manufactured implants.



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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 [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

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