

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 770239 R000

**Manufacturer:** BellaSeno GmbH

**Address:**

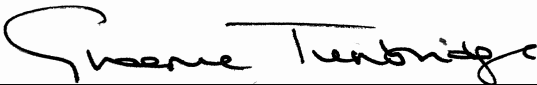
Deutscher Platz 5a  
Leipzig  
04103  
Germany

**Single Registration Number:** Not Available

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-12-12**

Current Issue Date: **2023-12-12**

Starting Validity Date: **2023-12-12**

Expiry Date: **2028-12-11**

...making excellence a habit.™

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 770239 R000

### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Custom-made Polycaprolactone Pectus Scaffold (PPS)	Custom-made Class III implantable
Custom-made Polycaprolactone Bones Scaffold (PBS)	Custom-made Class III implantable



First Issue Date: **2023-12-12**

Current Issue Date: **2023-12-12**

Starting Validity Date: **2023-12-12**

Expiry Date: **2028-12-11**

...making excellence a habit.™

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 770239 R000

### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3675011	Issued



First Issue Date: **2023-12-12**

Current Issue Date: **2023-12-12**

Starting Validity Date: **2023-12-12**

Expiry Date: **2028-12-11**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.