

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Parcus Medical LLC
6423 Parkland Drive
Sarasota
Florida
34243
USA

Facility ID Number: F007121

Holds Certificate No:

MDSAP 798896

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture and distribution of sterile and non- sterile interference screws, suture anchors, suspensory ligament devices, suture retention devices and associated single use and reusable instrumentation for the areas of orthopedics surgery and soft tissue reconstruction.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2024-01-22

Effective Date: 2024-01-22

Expiry Date: 2027-01-21



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 798896**

Location

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Registered Activities

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Final Packaging, Fished Goods Inventory, and office personnel such as Customer Service, Accounting, and Marketing.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.