

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Tyber Medical  
83 South Commerce Way  
Suite 310  
Bethlehem  
Pennsylvania  
18017  
USA

Facility ID Number: F001462

Holds Certificate No: **MDSAP 698605**

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

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

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

Design and manufacture of sterile and non-sterile orthopedic implants, screws and related accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-09-30

Effective Date: 2023-08-02

Expiry Date: 2025-07-27



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 2

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Certificate No: **MDSAP 698605**

Location	Registered Activities
Tyber Medical 83 South Commerce Way Suite 310 Bethlehem Pennsylvania 18017 USA Facility ID Number: F001462	Design and manufacture of sterile and non-sterile orthopedic implants, screws and related accessories.
Tyber Medical Bonita Springs 12702 Trade Way Dr Unit 3 and 4 Bonita Springs Florida 34135 USA Facility ID Number: F005204	Manufacture of non-sterile orthopedic implants, screws and related accessories.
Tyber Medical 89 South Commerce Way Suite 990 Bethlehem Pennsylvania 18017 USA Facility ID Number: F001462	Design and Development, Production (finished device, packaging/labeling), Preservation (storage / delivery), Purchasing, Monitoring and Measurement (verification of purchased product / processes, product), and Monitoring and Measurement (Final product release).
Tyber Medical Bonita Springs 12622 Trade Way Dr. Unit 6 Bonita Springs Florida 34135 USA Facility ID Number: F005204	Manufacture of non-sterile orthopedic implants, screws and related accessories.

Original Registration Date: 2019-09-30

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Page: 2 of 2

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](https://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.