By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Pioneer Surgical Technology Inc.
375 River Park Circle
Marquette
Michigan
49855
USA

Facility ID Number: F003064

Holds Certificate No: **MDSAP 700908**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 821

The design, development, manufacture and servicing of sterile and non-sterile, biological, non-resorbable and resorbable orthopedic and spinal implants and instruments that include such product families as spinal fusion, spinal arthroplasty, orthopedic retention, fracture fixation and sternal cable systems, including product category Greater Trochanteric Reattachment Device (GTR).

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-09-22 Effective Date: 2020-09-22 Expiry Date: 2023-09-21

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 700908**

Location	Registered Activities
Pioneer Surgical Technology Inc. 375 River Park Circle Marquette Michigan 49855 USA Facility ID Number: F003064	The design, development, manufacture and servicing of sterile and non-sterile, biological, non-resorbable and resorbable orthopedic and spinal implants and instruments that include such product families as spinal fusion, spinal arthroplasty, orthopedic retention, fracture fixation and sternal cable systems, including product category Greater Trochanteric Reattachment Device (GTR).
Pioneer Surgical Technology Inc. 1800 A North Greene St. Greenville North Carolina 27834 USA Facility ID Number: F003142	The design, development and manufacture of resorbable spinal and orthopedic bone graft substitutes utilizing synthetic powders and animal tissue materials and of non-resorbable spinal implants containing synthetic powders. The design and development of ancillary instrumentation.

Original Registration Date: 2020-09-22 Effective Date: 2020-09-22 Expiry Date: 2023-09-21