By Royal Charter

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Pioneer Surgical Technology Inc.
also doing business as Resolve
Surgical Technologies
375 River Park Circle
Marquette
Michigan
49855
USA

Facility ID Number: F003064

Holds Certificate No: **MDSAP 700908**

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, 21 CFR 821

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-09-22 Effective Date: 2023-09-22 Expiry Date: 2026-09-21



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

...making excellence a habit.™

Certificate No: **MDSAP 700908**

# Registered Scope:

The design, development, and manufacture 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).

Original Registration Date: 2020-09-22 Effective Date: 2023-09-22 Expiry Date: 2026-09-21