

# UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

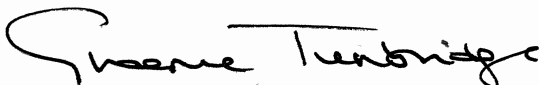
**No.** **UKCA 778529**  
**Issued To:** **Pioneer Surgical Technology Inc**  
**375 River Park Circle**  
**Marquette**  
**Michigan**  
**49855**  
**USA**

In respect of:

**The design and manufacture and final inspection of sterile Hip fixation implants**

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2022-11-18**

Date: **2024-06-17**

Expiry Date: **2029-06-18**

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## Supplementary Information to UKCA 778529

Issued To:

**Pioneer Surgical Technology Inc  
375 River Park Circle  
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USA**

Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
46647	Hip internal fixation system (GTR- Greater Trochanteric Reattachment)	Hip Fixation Implant

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## Certificate History

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### 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)*

Date	Reference Number	Action
2022-11-18	3757093	First Issue, Traceable to CE 52820
Current	30181405	Re-Issued – Certificate renewal Restricted – Removal of The design and manufacture and final inspection of; -sterile Porcine gelatin-based resorbable biological synthetic bone graft substitutes -non-sterile Orthopedics bone screw and washer implants -sterile Orthopaedic fixation cerclage wire/cable implant -sterile and non-sterile Spinal fixation cable implants -sterile and non-sterile Sternal fixation cable/plate implants

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Date	Reference Number	Action
		-non-sterile non-cervical Intervertebral spinal fusion implants -sterile Interbody fusion implants -sterile Interspinous lumbar decompression spacer implant -non-sterile instruments intended for connection to an active medical device -non-sterile single-use instruments Amended – GMDN 34003 (Hip internal fixation system) has been made obsolete by the GMDN Agency. GMDN 46647 (Orthopaedic fixation plate, nonbioabsorbable), has been assigned in its place.

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