By Royal Charter

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:

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375 River Park Circle
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Number	Device Name	Intended purpose per IFU
Class IIb		
46647	Hip internal fixation system (GTR-Greater Trochanteric Reattachment)	Hip Fixation Implant

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UKCA Certificate - Full Quality Assurance System 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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