



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. Issued To: UKCA 778529

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000 Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK. A member of BSI Group of Companies.





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Supplementary Information to UKCA 778529

Issued To:

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| Number | Device Name | Intended purpose per IFU | The second |
|-----------|---|--------------------------|------------|
| Class IIb | | | 2 Con |
| 46647 | Hip internal fixation system (GTR- Greater Trochanteric Reattachment) | Hip Fixation Implant | |

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: Date: Issued To: UKCA 778529

2024-06-17 Pioneer Surgical Technology Inc 375 River Park Circle Marquette Michigan 49855 USA

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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