

# 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]

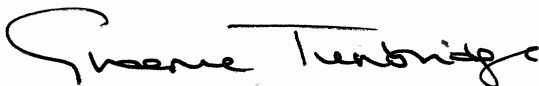
**No.** UKCA 772873  
**Issued To:** **Xiros Limited**  
**Springfield House**  
**Whitehouse Lane**  
**Yeadon**  
**Leeds**  
**LS19 7UE**  
**United Kingdom**

In respect of:

**The design and manufacture of sterile orthopaedic fixation devices, prosthetic ligaments and tapes, and surgical instruments**

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 Medical Devices

First Issued: **2022-07-21**

Date: **2024-03-14**

Expiry Date: **2029-01-10**

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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 772873

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| Device Code      | Device Name                         | Intended purpose per IFU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Class IIb</b> |                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GMDN 47030       | JewelACL™                           | The JewelACL is intended to be used for reconstruction of the anterior cruciate ligament.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| GMDN 46242       | Poly-Tapes and Infinity-Lock™ Tape  | These are single use devices intended to be used for tissue approximation in orthopaedic procedures, including use in reconstructing damaged or torn ligaments or tendons according to the surgeon's own preferred technique and at his/her discretion.<br>Also supplied for soft tissue (tendon and ligament) fixation to bone during orthopaedic reconstruction procedures.                                                                                                                                                                                                                                             |
| GMDN 46242       | Pitch-Patch                         | The Pitch-Patch is a single use device intended to be used for reinforcement of the rotator cuff following or during repair by suture or suture anchors, where weakness exists in the soft tissue.<br><br>The Pitch-Patch is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the repair. The Pitch-Patch reinforces the rotator cuff and provides a scaffold that is incorporated into the patient's own tissue. |
| GMDN 46242       | AchilloCordPLUS™ System Implant Set | The AchilloCordPLUS is intended to be used in the repair of acute Achilles tendon ruptures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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| Device Code      | Device Name                            | Intended purpose per IFU                                                                                                                                                                                                  |
|------------------|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| GMDN 46242       | QuadsTape System™                      | The QuadsTape and PatellarTape Systems are intended for reconstruction of the quadriceps and patellar tendons respectively.                                                                                               |
| GMDN 46242       | PatellarTape System™                   |                                                                                                                                                                                                                           |
| GMDN 62000       | Infinity-Lock™ Button System           | The Infinity-Lock Button System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption. |
| <b>Class IIa</b> |                                        |                                                                                                                                                                                                                           |
| MD 0106          | Sterile surgical instruments           | ---                                                                                                                                                                                                                       |
| MD 0106          | Sterile surgical instruments - textile | ---                                                                                                                                                                                                                       |

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## Certificate History

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| Date       | Reference Number | Action                                                                                     |
|------------|------------------|--------------------------------------------------------------------------------------------|
| 2022-07-21 | 3699784          | First Issue; Traceable to CE 00458                                                         |
| 2023-06-12 | 30000215         | Removal of Also Trading as: Neoligaments™, a division of Xiros from Legal Manufacture name |
| 2023-12-15 | 30003267         | Renewal of the certificate                                                                 |
| Current    | 30076776         | Removal of Tube Tape (Class IIb) device                                                    |

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