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 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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Supplementary Information to UKCA 772873

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Device Code	Device Name	Intended purpose per IFU
Class IIb		
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. 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. 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.
Class IIa		
MD 0106	Sterile surgical instruments	---
MD 0106	Sterile surgical instruments - textile	---

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UKCA Certificate - Full Quality Assurance System 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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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.
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