EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00458**

Issued To: **Xiros Limited**
Also Trading as:
Neoligaments™, a division of Xiros
Springfield House
Whitehouse Lane
Yeadon, Leeds
LS19 7UE
United Kingdom

In respect of:

The design and manufacture of sterile and non 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 Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1995-01-11** Date: **2020-11-24** Expiry Date: **2024-01-10**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00458**

Date: **2020-11-24**

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Date	Reference Number	Action
11 January 1995	-	First Issued.
07 February 2001	-	Company name change.
16 June 2004	-	Company address change and Certificate renewal.
14 March 2006	-	Change to sub-contractor address (Xiros).
24 April 2006	-	Removal of the Xiros Derby site as a sub-contractor.
26 January 2009	7214752	Certificate renewal. Address has been modified from "White House Lane" to "Whitehouse Lane."
29 September 2009	7437575	Company name changed from "Xiros PLC" to "Xiros Limited"
08 November 2010	7602685	Company name change from "Xiros Limited" to "Xiros Limited Also Trading as: Neoligments™, a devision of Xiros"
08 January 2014	8095330	Certificate Renewal. Change of name of significant subcontractor from ISOTRON PLC to Synergy Health.

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Date	Reference Number	Action
04 January 2019	9625058	Certificate Renewal. Removal of critical subcontractor 'Synergy Health Sterilisation UK Ltd, Bradford' for the activity of Sterilisation. Addition of critical subcontractor 'Synergy Health Sterilisation UK Ltd, (Synergy Health – AST – Daventry), Brunel Close, Drayton Fields Industrial Estate, Daventry, NN118RB, UK' for the activity of Sterilisation.
12 February 2019	7779001	Traceable to NB 0086.
21 November 2019	3069877	Addition of critical subcontractor 'Synergy Health Sterilization UK Ltd, Moray Road, Swindon' for the activity of Gamma Sterilisation Addition of critical subcontractor 'Systagenix Wound Management Limited, Gargrave' for the activity of Gamma Sterilisation
24 November 2020	3328155	Addition of Advena Limited for the activity of EU representative.

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
12 June 2023	30000287	Removal of Also Trading as: Neoligaments™, a division of Xiros from Legal Manufacture name
20 February 2024	30076822	Removal of the following devices: 102-1142 AchilloCordPLUS System Implant Set (Class IIb), 102-1062 PatellarTape System (Class IIb), 102-1061 QuadsTape System (Class IIb), 202-1205 Infinity-Lock Button System Instrument Set (Class IIa), 202-1204 Infinity-Lock Button System Button (Class IIb), 102-1204 Infinity-Lock Button System Tape (Class IIb) and 102-1040 Tube Tape (Class IIb)

Inspiring trust for a more resilient world.

20 February 2024

Xiros Limited
Springfield House
Whitehouse Lane
Yeadon, Leeds
LS19 7UE
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 00458	93/42/EEC Annex II excluding Section 4	30076822	Removal of the following devices: 102-1142 AchilloCordPLUS System Implant Set (Class IIb), 102-1062 PatellarTape System (Class IIb), 102-1061 QuadsTape System (Class IIb), 202-1205 Infinity-Lock Button System Instrument Set (Class IIa), 202-1204 Infinity-Lock Button System Button (Class IIb), 102-1204 Infinity-Lock Button System Tape (Class IIb) and 102-1040 Tube Tape (Class IIb)

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices