

# 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: **2019-11-21**

Expiry Date: **2024-01-10**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Synergy Health Sterilisation UK Ltd ( Synergy Health - AST-Daventry ) Brunel Close Drayton Fields Industrial Estate Daventry Northamptonshire NN11 8RB United Kingdom	<b>Gamma Sterilization</b>
Synergy Health Sterilization UK Ltd Moray Road, Elgin Industrial Estate, Swindon SN2 8XS, United Kingdom	<b>Gamma Sterilization</b>

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**Subcontractor:**

**Service(s) supplied**

Systagenix Wound Management Limited  
(an affiliate of Systagenix Wound Management  
Manufacturing Limited)  
Gargrave,  
North Yorkshire,  
BD23 3RX,  
United Kingdom

**Gamma Sterilization**

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# EC Certificate - Full Quality Assurance System Certificate History

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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: Neoligaments™, a division 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.
Current	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