

EC Certificate - Full Quality Assurance System

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

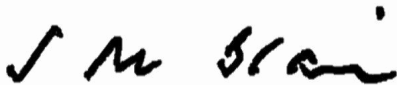
No. CE 00458
Issued To: **Xiros Limited**
Also Trading as:
Neoligaments™, a division of Xiros
Springfield House
Whitehouse Lane
Yeadon, Leeds
LS19 7UE
United Kingdom

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **1995-01-11**

Date: **2019-01-04**

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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Subcontractor:

Service(s) supplied

Synergy Health Sterilisation UK Ltd
(Synergy Health – AST – Daventry)
Brunel Close
Drayton Fields Industrial Estate
Daventry
NN11 8RB
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
Current	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.