By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 512608**

Issued To: **X-Spine Systems, Inc.**
452 Alexandersville Rd.
Miamisburg
Ohio
45342
USA

In respect of:

The design, development, and manufacture of non-sterile and sterile spinal plating systems, spinal screw systems, including occipital plates and screws, spinal fusion systems and sacroiliac joint fusion systems

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):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **10 October 2007** Date: **29 February 2016** Expiry Date: **09 October 2017**

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
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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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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Date:	**29 February 2016**
Issued To:	**X-Spine Systems, Inc.** **452 Alexandersville Rd.** **Miamisburg** **Ohio** **45342** **USA**

Subcontractor:	**Service(s) supplied**
Acero Precision, Inc. 1340 Enterprise Drive West Chester Pennsylvania 19380 USA	**Manufacture**
APS Materials, Inc 4011 Riverside Drive Dayton OH 45405 USA	**Other critical processes**
Emergo Europe Molenstraat 15 2513 BH, The Hague Netherlands	**EU Representative**

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Subcontractor:	**Service(s) supplied**
Hammill Manufacturing Company 360 Tomahawk Drive Maumee Ohio 43537 USA	**Manufacture**
Invibio Device Component Manufacturing Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom	**Manufacture**
LH Medical Corporation 6932 Gettysburg Pike Fort Wayne Indiana 46804 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Life Science Outsourcing, Inc 830 Challenger Street Brea California 92821 USA	**Packaging**
Micropulse 5865 East State Road 14 Columbia City IN 46725 USA	**Manufacture**
Norwood Medical 2122 Winners Circle Dayton Ohio 45401 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Precision Medical Technologies Inc. 2059 North Pound Drive Warsaw Indiana 46582 USA	**Manufacture**
Quality Tech Services Inc. 10525 Hampshire Avenue Bloomington Minnesota 55438 USA	**Packaging**
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 305 Enterprise Drive Westerville Ohio 43081 USA	**Gamma Sterilization**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
STERIS Isomedix Services 1000 South Sarah Place Ontario California 91761 USA	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Surface Dynamics LLC 231 Northland Blvd Cincinnati Ohio 45246 USA	**Other critical processes**
Vistek Medical 153 Railroad Drive Ivyland, PA 18974 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 512608**

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Date	Reference Number	Action
10 October 2007	4904082	First issue
24 March 2009	7341048	Scope clarification, addition of word "system" for Spider Cervical and Capless Pedicle Screw
27 January 2010	7464490	Scope clarification, additional of word "Non-sterile"; Extension to scope to include Calix Spinal Implant System, Butrex Buttress Plating System and X90 Pedicle Screw System Removal of sub contractors, Advantis Medical, In-Tech Medical, Leis Medical, Inc. and Pulse Technologies Addition of sub contractors, Emergo Europe for EU Rep. Invibio Ltd., Hammill Manufacturing Company and Norwood Medical for Manufacturing sub contractor activity.
08 November 2010	7602520	Certificate scope revised. From: The design, development, and manufacture of the non-sterile Butrex Buttress Plating System, Calix Spinal Implant System, Capless and X90 Pedicle Screw System, and Spider Cervical Plating System. To: The design, development, and manufacture of non-sterile spinal plating systems, spinal screw systems, and spinal fusion systems. Addition of 'Vorzeigen Medical, Inc., IN 47331, USA' as manufacturing sub contractor to significant list of sub contractors.

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Date	Reference Number	Action
27 July 2011	7701432	Addition of significant subcontractors "Vistek Medical, 153 Railroad Drive, Ivyland, PA 18974,USA" for manufacturing activities. " In-Tech Medical, 2851 Lamp Place, Suite 15, Memphis TN 38118, USA" for manufacturing activities. Inclusion of Axle Interspinous Fusion System to scope for "spinal fusion systems" (ref: SMO 7475185).
09 October 2012	7906573	Certificate Renewal Removal of significant subcontractor 'Vorzeigen Medical, Inc., IN 47331, USA' for manufacturing activity.
25 October 2013	8011717	Extended scope to cover sacroiliac joint fusion systems. Added Surface Dynamics – Cincinnati, Surface Dynamics – Memphis, LH Medical, APS Materials and Micropulse to the listing of significant subcontractors
12 November 2015	8333444	Following a technical file scope extension review for Certex OCT (SMO 8333444) occipital plates and screws are being added to the scope of the certificate. Addition of significant subcontractors Precision Medical Technologies Inc. and Acero Precision, Inc.; as well as the removal of Surface Dynamics Memphis, LLC., and In-Tech Medical (Memphis, TN)

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Date	Reference Number	Action
29 February 2016	8122125	Following a technical file scope extension review for a gamma sterilized stand-alone lumbar intervertebral body fusion cage, Irix-A, and associated microbiology assessment (SMO 8254807 and SMO 8255014 respectively) the words 'and sterile' were added to the scope of the certificate. Addition of significant subcontractors Life Science Outsourcing, STERIS Isomedix Services (Ontario, CA), Sterigenics US (Corona, CA), Sterigenics US, LLC (Gurnee, IL & Westerville, OH) and Quality Tech Services, Inc. Addition of extended Xpress screw lengths to include 60-100 mm length and expanded Indication for Use to allow Iliac fixation, per technical file review SMO 8433165