

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):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2007-10-10**

Date: **2017-10-27**

Expiry Date: **2022-10-09**

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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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Date: **2017-10-27**
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Subcontractor:	Service(s) supplied
Acero Precision, Inc. 1340 Enterprise Drive West Chester Pennsylvania 19380 USA	Manufacture
AeroMed, Inc. 2342 North Penn Road Hatfield Pennsylvania 19440 USA	Manufacture
APS Materials, Inc 4011 Riverside Drive Dayton OH 45405 USA	Other critical processes

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Subcontractor:	Service(s) supplied
Axial Medical 65 Richard Rd. Ivyland Pennsylvania 18974 USA	Manufacture
DRT Medical LLC 4201 Little York Road Dayton Ohio 45414 USA	Manufacture
Emergo Europe Prinsessegracht 20 2514 AP The Hague The 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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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
Sites Medical 5865 East State Road 14 Columbia City Indiana 46725 USA	Manufacture

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	Gamma Sterilization
Sterigenics US, LLC 305 Enterprise Drive Westerville Ohio 43081 USA	Gamma Sterilization
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization

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Subcontractor:

Service(s) supplied

STERIS Isomedix Services
1000 South Sarah Place
Ontario
California
91761
USA

Gamma Sterilization

Surface Dynamics LLC
231 Northland Blvd
Cincinnati
Ohio
45246
USA

Other critical processes

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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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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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29 February 2016	8122125	<p>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.</p> <p>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.</p> <p>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</p>

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Current	8748485	Certification Renewal Added the following subcontractors (all USA based and all for 'manufacture' service): <ul style="list-style-type: none"> • Axial Medical, Ivyland, PA • DRT Medical LLC, Dayton, OH • Sites Medical, Columbia City, IN • AeroMed, Inc., Hatfield, PA Removed subcontractor: Vistek Medical, 153 Railroad Drive, Ivyland, PA 18974, USA EU Rep, Emergo Europe, address change to Prinsessegracht 20, 2514 AP The Hague, The Netherlands