

EC Certificate - Full Quality Assurance System

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

No.**CE 549384****Issued To:**

**Integra LifeSciences Corporation
4900 Charlemar Drive, Bldg A.
Cincinnati
Ohio
45227
USA**

In respect of:

Design, development and manufacture of non-sterile reusable skull pins for end user sterilization, sterile disposable skull pins, joint implant systems, and surgical retractor systems; sterile single use head ring screws and biopsy needles.

Those aspects of Annex II related to metrology in the manufacture of stereotactic instrumentation.

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: **2009-06-29**

Date: **2020-04-10**

Expiry Date: **2024-05-26**

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Page 1 of 1

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:

Certificate No: **CE 549384**
 Date: **2020-04-10**
 Issued To: **Integra LifeSciences Corporation**
4900 Charlemer Drive, Bldg A.
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Subcontractor:

Service(s) supplied

Dadson Manufacturing Corporation
 dba JE Petersen
 1109 NW Valley Ridge Drive
 Grain Valley
 Missouri
 64029
 USA

Manufacture

DSM Biomedical, Inc.
 d.b.a. DSM Biomedical
 DSM Biomedical, Inc.
 d.b.a. Actamax Surgical Materials, LLC
 735 Pennsylvania Drive
 Exton
 Pennsylvania
 19341
 USA

**Manufacture
Packaging**

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Subcontractor:	Service(s) supplied
DSV Solutions N.V. Kenedy Industriepark Eddastraat 21 B-9042 Gent Belgium	Final Inspection
Integra LifeSciences Corporation (Integra Pain Management) 3498 West 2400 South # 1050 West Valley City Utah 84119 USA	Packaging
Integra LifeSciences Services France Immeuble Séquoia 2 97 allée Alexandre Borodine Parc Technologique de la Porte Des Alpes 69800 Saint Priest France	EU Representative

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Subcontractor:	Service(s) supplied
Integra NeuroSciences State Road 402, Km 1.2 Añasco 00610 Puerto Rico	Packaging
Orchid Chelsea a division of Orchid Orthopedic Solutions LLC 13800 Luick Dr Chelsea Michigan 48118 USA	Manufacture
Orchid MPS A division of Orchid Orthopedic Solution, LLC 3233 W. Harvard Street Santa Ana California 92704 USA	Manufacture

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Subcontractor:	Service(s) supplied
Orchid Orthopedic Solutions LLC 23149 Commerce Drive Farmington Hills Michigan 48335-2723 USA	Manufacture Packaging
Orchid Orthopedic Solutions Memphis Location 4600 E. Shelby Drive Suite 1 Memphis Tennessee 38118 USA	Manufacture Surface Treatment
Paragon Medical Inc 8 Matchett Dr Pierceton Indiana 46562 USA	Manufacture

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Subcontractor:

Service(s) supplied

Pro-Tech Design and Manufacturing, Inc.
 14561 Marquardt Ave.
 Sante Fe Springs
 California
 90670
 USA

Other Critical Processes
Packaging

Sterigenics US, LLC
 344 Bonnie Circle
 Corona
 California 92880
 USA

Gamma Sterilization

Sterigenics US, LLC
 5725 West Harold Gatty Drive
 Salt Lake City
 Utah
 84116
 USA

ETO Sterilization

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Subcontractor:

Service(s) supplied

STERIS Isomedix Services, Inc.
 2072 Southport Road
 Spartanburg
 South Carolina
 29306
 USA

ETO Sterilization

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Date	Reference Number	Action
29 June 2009	7360947	Transfer and merger of certificates from TuV; Certificate Numbers 30492532 002, 30590021 001 and DM 707024. Subcontractor 'Integra Neurosciences Ltd, SP10 4DR' is EU Representative for neuro-surgical products. Subcontractor 'NewDeal, 69006 France' is EU Representative for orthopaedic products.
08 April 2010	7478594	Renewal of certificate. Removal of subcontractor NewDeal and addition of subcontractors Integra LifeSciences Services France, Millstone Medical Outsourcing, PTI Engineered Plastics and Nemcomed. Minor amendment to scope to change 'reusable skull pins' to 'non-sterile reusable skull pins for end user sterilization'.
September 2012	7903834	Addition of Significant subcontractor 'DSV Solutions N.V., Kennedy Industriepark, Eddastraat 21, 9042 Gent, Belgium' for final inspection activity.
02 October 2012	7900436	'Scope extension to include table mounted retractor systems'.
01 February 2013	7944450	Scope extension to include 'non-sterile spinal fixation systems for end user sterilization' as transferred from CE 02185. Addition of SeaSpine, Inc., 2302 La Mirada Drive, Vista, California, 92081-7862, USA for the activities of Design, Development and Regulatory Compliance.

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Page 1 of 6

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Date	Reference Number	Action
05 June 2015	8322160	Certificate Renewal. Removal of significant subcontractors: 'Integra Neurosciences, Newbury Road, Andover, Hampshire, SP10 4DR, United Kingdom' for the activity EU Rep. 'Kinamed Incorporated, 820 Flynn Road, Camarillo, CA 93012 8701, USA' for the activity Manufacture. 'Sterigenics US, LLC, 305 Enterprise Drive, Westerville, Ohio 43081, USA' for the activity Gamma sterilization. 'SteriTech, Inc., Carr. 701, km 0.7, Salinas Industrial Park, Salinas, 00751, Puerto Rico' for the activity ETO Sterilization. 'Mark Machine, A Division of Paragon Medical, Inc., 50 Dwight Place, New Jersey 07004, USA' for the activity Manufacture. 'Millstone Medical Outsourcing LLC, 580 Commerce Drive, Fall River, Massachusetts 02720 4759, USA' for the activity Packaging. 'Nemcomed, 801 Industrial Drive, Hicksville, Ohio 43526 USA' for the activity Manufacture. Update of significant subcontractor 'Special Team Medical Services' name to 'Desco Industries, Inc. dba Specialteam'.

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Page 2 of 6

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05 June 2015	8322160	Update of significant subcontractors: 'Orchid MPS, A division of Orchid Orthopedic Solutions LLC 30331 Esperanza Rancho Santa Margarita' to 'Orchid Santa Ana a division of Orchid Orthopedic Solutions LLC 3233 West Harvard Street Santa Ana, CA 92704 USA'. Update of significant subcontractor 'Orchid Orthopedic Solutions Chelsea, LLC 13800 Luick Drive, Chelsea Michigan 48118 USA' to 'Orchid Chelsea a division of Orchid Orthopedic Solutions LLC, 13800 Luick Dr, Chelsea MI 48118 USA'. Addition of significant subcontractors: 'Integra LifeSciences Corporation (Integra Pain Management), 3498 West 2400 South # 1050, West Valley City, UT 84119, USA' for the activity Packaging. 'Paragon Medical Inc; 8 Matchett Dr., Pierceton, IN, USA' for the activity Manufacture. 'Kensey Nash Corporation, d.b.a. DSM Biomedical, 735 Pennsylvania Drive, Exton, Pennsylvania, 19341 USA' for the activities Manufacture and Packaging. 'STERIS Isomedix Services, 1880 Industrial Drive, Libertyville, Illinois, 60048, USA' for the activity Gamma sterilization.
05 June 2015	8322160	'Orchid Orthopedic Solutions, Memphis Location, 4600 E. Shelby Drive, Suite 1, Memphis, Tennessee, 38118, USA' for the activity Manufacture 'Orchid BioCoat, 21249 Bridge Street, Southfield, Michigan, 48034, USA' for the activity Packaging. 'Pro-Tech Design and Manufacturing, Inc.; 14561 Marquardt Ave.; Santa Fe Springs, CA 90670 USA' for the activity Packaging. 'Sterigenics US, LLC; 5725 Harold Gatty Drive; Salt Lake City, UT 84116, USA' for the activity ETO sterilization. 'Steris Isomedix Services, 2072 Southport Road, Spartanburg, SC 29306, USA' for the activity ETO sterilization.

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Page 3 of 6

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07 December 2015	8431160	Scope extension to include "Design, development and manufacture of Stereotactic instrumentation and software; sterile single use head ring screws and biopsy needles". Removal of "non-sterile spinal fixation systems for end user sterilization" from scope of certification. Addition of significant subcontractors: NeedleTech Products Inc. 452 John L Dietsch Boulevard Attleboro Massachusetts 02763 USA as significant subcontractor for the activity Manufacture. C&J Industries Inc. 760 Water Street Meadville, PA 166335 USA as significant subcontractor for the activity Manufacture. Removal of significant subcontractor: SeaSpine, Inc. 2302 La Mirada Drive Vista, CA 92081-7862 USA for the activities Design, Development, and Regulatory compliance.
07 September 2017	8760903	Addition of significant subcontractor "Integra Burlington MA, 85 Rangeway Rd., Billerica, Massachusetts, 01862, USA" for the activities Design and Development.
12 March 2019	7781091	Traceable to NB 0086.

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Page 4 of 6

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Date	Reference Number	Action
Current	3058371	Certificate Renewal. Removal of subcontractors/suppliers: C & J Industries, Edwards Lifesciences, Desco Industries, Integra Burlington MA, NeedleTech Products, Inc., PTI Engineered Plastics, STERIS Isomedix Services - Libertyville, IL location only, and Integra LifeSciences (dba Integra NeuroSciences) Supplier/Subcontractor name changes: Dadson Manufacturing corporation dba Epic medical concepts and innovations changed to Dadson Manufacturing Corporation dba JE Petersen; Kensey Nash Corporation d.b.a. DSM Biomedical changed to DSM biomedical , Inc. d.b.a. DSM Biomedical DSM Biomedical , Inc. d.b.a. Actamax Surgical Materials, LLC; Orchid Biocoat to Orchid Orthopaedic Solutions LLC; Orchid Santa Ana , a division of Orchid Orthopaedic Solutions LLC to Orchid MPS a division of Orchid Orthopaedic Solutions, LLC; Address changes: Minor changes to existing addresses of Dadson Manufacturing Corporation, DSV Solutions N.V., Integra Lifesciences Services France, Paragon medical Inc, PTI Engineered Plastics Address changes for Orchid Orthopaedic Solutions LLC from 21249 Bridge Street Southfield Michigan 48034 USA to 23149 Commerce Drive, Farmington Hills, 48335-2723, USA Changes to subcontracted activities: Orchid Orthopaedic Solutions LLC - addition of Manufacture; Orchid Orthopaedic solutions (Memphis) - addition of surface treatment; Pro-Tech Design and Manufacturing, Inc – Addition of Other critical processes

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Page 5 of 6

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		Scope change from: Design, development and manufacture of non-sterile reusable skull pins for end user sterilization, sterile disposable skull pins, cubital and carpal tunnel release systems, wrist fusion systems, joint implant systems, toe implants, compression screws, bone fixation devices, cement restrictors, and surgical retractor systems, powered dermatomes and dermatome blades; stereotactic instrumentation and software; sterile single use head ring screws and biopsy needles. To: Design, development and manufacture of non-sterile reusable skull pins for end user sterilization, sterile disposable skull pins, joint implant systems, and surgical retractor systems; sterile single use head ring screws and biopsy needles. Those aspects of Annex II related to metrology in the manufacture of stereotactic instrumentation.
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