EC Certificate

List of Significant Subcontractors

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

Certificate No. **CE 53820**
Date: **5 May 2005**
Issued to: **DePuy Spine**
Raynham

Subcontractor	Service(s) supplied
DePuy (Ireland) Limited Ringaskiddy Cork Ireland	Manufacture
Waldemar Link GmbH & Co. KG Barkhausenweg Hamburg Germany 22339	Manufacture
DePuy Spine 365 Ravendale Road Mountain View CA 94043 USA	Manufacture
Titan Scan Systems 920 Activity Road, Suite D San Diego CA 92121 USA	Sterilization
DePuy Spine Inc St Anthony's Road Leeds United Kingdom LS11 8DT	Design

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Maylands Avenue, Hemel Hempstead, Hertfordshire HP2 4SQ United Kingdom
Tel +44 (0)1442 230442 www.bsi-global.com
BSI Group Headquarters: 389 Chiswick High Road, London W4 4AL Tel: (0)208 996 9000

EC Certificate

[redacted]

Full Quality Assurance

No. CE 53820

Issued to:

DePuy Spine
325 Paramount Drive
Raynham
Massachusetts
02767
USA

In respect of:
The design, development and manufacture of spinal implant systems and instrumentation systems, synthetic bone graft material and cement delivery systems.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

[redacted]

First Issued: **4 Mar 2000** Date: **5 May 2005**

Expiration Date: **3 Mar 2010**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.
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.

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[redacted]

History

CN=Cathie Stoffell/OU=TGA/O=Health

Certificate issued under:	Council Directive 93/42/EEC (MDD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	BSI Product Services [0086] Lookup
Certificate number:	CE 53820
Certificate issue date: (dd/mm/yyyy)	04/03/2000
Certificate expiry date: (dd/mm/yyyy)	03/03/2010
Certificate re-issue date: (dd/mm/yyyy)	05/05/2005

Restrictions on scope:

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.
Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents — EC Certificate - CE 53820_DePuy Spine_Exp 3Mar10.pdf

Supporting documents:

#	Document Type	Description	Method
1.	Addition of GMDN code(s)	Word Document	Fax

Related Active ARTG Entry Information:

[redacted]

Manufacturer Evidence

Status : Versioned

Certificate change history

[redacted]

Notification details

Evidence identifier:	021112-WEBE-5FT7L4
Submission identifier:	DV-2005-5669
Version number:	10
Sponsor's own reference:	DePuy Spine Inc Annex II

Sponsor details

Agent name:	
Sponsor name:	Johnson & Johnson Medical Pty Ltd T/A Depuy Australia
Contact details:	[redacted]

Certification details

Manufacturer name:	Depuy Spine Inc. (United States Of America)[42419]
Manufacturer address as on certification:	325 Paramount Drive Raynham Massachusetts 02767 United States Of America
Type of product:	

○ This certification is to support an application for an in vitro diagnostic medical device (IVD)

● This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate

History of Quality Assurance Certificate

Certificate No: CE 53820

Issue Date:

Issued to: DePuy Spine
Raynham
USA

Date	BSI Reference No.	Action
12 April 2011	7652447	Revision of scope, from 'The design, development and manufacture of spinal implant systems and instrumentation systems, synthetic bone graft material, spinal cement and cement delivery systems and accessory needles' to 'The design, development and manufacture of spinal implant systems and instrumentation systems, bovine-derived bone graft material, spinal cement delivery systems and accessory needles.'

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Certificate

History of Quality Assurance Certificate

Certificate No: **CE 53820**

Issue Date:

Issued to: **DePuy Spine**
Raynham
USA

Date	BSI Reference No.	Action
7 April 2008	7177220	Extension to scope to include "Spinal Cement" Addition of subcontractor Disc-o-Tech Medical Technologies Ltd., for the activities of design and manufacture
13 August 2008	7217964	Removal of DePuy Orthopaedics, Inc. from the list of significant subcontractors for manufacturing. Addition of BeamOne to the list of significant subcontractors for sterilization and Symmetry Medical, Inc. to the list of significant subcontractors for manufacturing.
6 October 2008	7265920	Addition of Mediplast Israel Ltd, Sor-Van Radiation Ltd, and Leoni Studer AG Studer Hard to the list of significant subcontractors for sterilization.
27 March 2009	7341322	Addition of DePuy Motion SARL to the list of significant subcontractors for manufacture. Addition of design activity for existing subcontractor DePuy Spine SARL. Addition of Sterigenics, San Diego, to the list of significant subcontractors for E-beam sterilization. Removal of Disc-O-Tech Medical, Symmetry Medical, and DePuy Spine Leeds from the list of significant subcontractors.
26 February 2010	7459365	Certificate renewal Inclusion of 'accessory needles' in the scope Addition of 'DePuy Int. for EU Rep. Deletion of Waldemar Link GmbH & Co., KG & J & J Medical, Germany. Minor changes to several sub contractors' addresses to match their current ISO 13485 certificates.

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Certificate

History of Quality Assurance Certificate

Certificate No: CE 53820

Issue Date:

Issued to: DePuy Spine
Raynham
USA

Date	BSI Reference No.	Action
04 March 2000	-	First issue
01 November 2002	-	DePuy Inc (Bridgewater) added as a subcontractor DePuy Acromed, Inc (Jacksonville) removed from the list of subcontractors
21 November 2003	-	Change of company name, change of scope and addition of DePuy Spine (Mountain View), titan Scan Systems (San Diego) and DePuy Spine Inc (Leeds) to the list of subcontractors
18 August 2004	-	Addition of DePuy (Ireland) Limited (Cork), Waldemar Link GmbH & Co. KG (Germany) and Isotron Plc (Reading) to the list of subcontractors
18 April 2005	-	Addition of Ethicon GmbH (Norderstedt), Steris/Isomedix (Massachusetts), and DePuy Spine SARL (Switzerland) as subcontractors and five year renewal
5 May 2005	-	Alignment with CE 79912 following completion of SER for Healos II Devices and addition of Kensey Nash Corporation as a subcontractor for Animal Substances.
19 June 2006	-	Addition of DePuy Orthopaedics New Bedford as a subcontractor for manufacture
20 March 2007	-	Sub-contractor company name change from "Titan Scan Systems" to "BeamOne LLC" and typographical error correction to address of BeamOne LLC

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 53820**
Date: **12 Apr 2011**
Issued to: **DePuy Spine**
Raynham
USA

Subcontractor	Service(s) supplied
Beam One LLC 500 West 4th Street Lima OH 45804 USA	Sterilization
RSI Leasing, Inc. dba Sterigenics 7695 Formula Place San Diego California 92121 USA	E beam Sterilization

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 53820**
Date: **12 Apr 2011**
Issued to: **DePuy Spine**
Raynham
USA

Subcontractor	Service(s) supplied
Steris Isomedix Services 435 Whitney Street Northborough Massachusetts 01532 USA	ETO Sterilization Gamma Sterilization
Kensey Nash Corporation 735 Pennsylvania Ave. Exton PA 19341 USA	Animal substances
Mediplast Israel Ltd. 7 Ha'yarkon Street P. O. Box 13214 Industrial Zone Yavne 81227 Israel	Sterilization
Sor-Van Irradiation Ltd. Kiryat Soreq PO Box 214 Yavne 81800 Israel	Sterilization

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 53820**
Date: **12 Apr 2011**
Issued to: **DePuy Spine**
Raynham
USA

Subcontractor	Service(s) supplied
DePuy Spine 365 Ravendale Road Mountain View CA 94043 USA	Manufacture
BeamOne LLC 9020 Activity Road, Suite D San Diego CA 92126 USA	Sterilization
Isotron PLC Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	Sterilization
DePuy Inc. 50 Scotland Park Drive Bridgewater Massachusetts USA 02324	Distribution Packaging Inspection

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 53820**
Date: **12 Apr 2011**
Issued to: **DePuy Spine**
Raynham
USA

Subcontractor	Service(s) supplied
Leoni Studer AG Studer Hard 4658 Däniken Switzerland	Sterilization
DePuy International Limited St Anthony's Road Leeds United Kingdom LS11 8DT	EU Representative
DePuy Motion SARL Chemin Blanc 38 CH-2400 Le Locle Switzerland	Manufacture
DePuy Spine SARL Chemin Blanc 36 CH 2400 Le Locle Switzerland	Design Manufacture
DePuy (Ireland) Loughbeg Ringaskiddy Cork Ireland	Manufacture

Certificate

Full Quality Assurance

[redacted]

No. CE 53820

Issued to:

DePuy Spine
325 Paramount Drive
Raynham
Massachusetts
02767
USA

In respect of:

The design, development and manufacture of spinal implant systems and instrumentation systems, bovine-derived bone graft material, spinal cement delivery systems and accessory needles

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

[redacted]

First Issued: **4 Mar 2000** Date: **12 Apr 2011**

Expiration Date: **3 Mar 2015**

Conditions of Approval
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PS1023/1210/AP

03/12/2002

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

[redacted]

121184	Depuy Australia Pty Ltd - Prosthesis, internal, spine, disc

[redacted]

History

Manufacturer Evidence

Status : Versioned

Certificate change history

Date received : 26/11/2002

Certificate printed : No

New Notification

Notification details

Evidence identifier: 021112-WEBE-5FT7L4

Version number: 1

Sponsor's own reference: DePuy Acromed, Inc

Sponsor details

Agent name:

Sponsor name: DEPUY AUST P/L

Contact details: [redacted]

Certification details

Manufacturer name: DEPUY ACROMED (United States Of America)[31232]

Manufacturer address as on certification: 325 PARAMOUNT DRIVE MASSACHUSETTS United States Of America S[91

Type of product:

○ This certification is to support an application for an in vitro diagnostic medical device (IVD)

● This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under: Council Directive 93/42/EEC (MDD)

Conformity assessment procedure: Schedule 3 Part 1 (Annex II)

Source of certification: BSI Product Services [0086] Lookup

Certificate number: 53820

Certificate issue date: (dd/mm/yyyy) 04/04/2000

Certificate expiry date: (dd/mm/yyyy) 04/04/2005

Certificate re-issue date: (dd/mm/yyyy)

Restrictions on scope:

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.
Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents

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Date: **5 May 2005**

Issued to: **DePuy Spine**
Raynham

Subcontractor	Service(s) supplied
Ethicon GmbH Robert-Koch-Strasse 1 Norderstedt Germany 22851	Sterilization
DePuy Spine SARL Chemin Blanc 36 CH 2400 Le Locle Switzerland	Manufacture
Isotron PLC Marcus Close Tilehurst Reading Berkshire United Kingdom RG30 4EA	Sterilization
DePuy Inc 50 Scotland Park Drive Bridgewater Massachusetts USA 02324	Distribution Final Inspection Packaging

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Certificate No. **CE 53820**
Date: **5 May 2005**
Issued to: **DePuy Spine**
Raynham

Subcontractor	Service(s) supplied
Steris Corporation Isomedix Services 435 Whitney Street Northborough Massachusetts USA 01532	Sterilization
Kensey Nash Corporation 55 East Uwchlan Avenue Exton PA 19341 USA	Animal substances

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EC Certificate

History of Quality Assurance Certificate

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Issued to: **DePuy Spine, Inc**
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Date	Action
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