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

Waldemar Link GmbH & Co. KG

Barkhausenweg

Hamburg

Germany

22339

DePuy Spine

365 Ravendale Road

Mountain View

CA 94043

USA

Titan Scan Systems

920 Activity Road, Suite D

San Diego

CA 92121

USA

DePuy Spine Inc

St Anthony's Road

Leeds

United Kingdom

LS11 8DT

Manufacture

Manufacture

Manufacture

Sterilization

Design

Page: 1 of 3



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):

First Issued: 4 Mar 2000

Date: 5 May 2005

Expiration Date: 3 Mar 2010

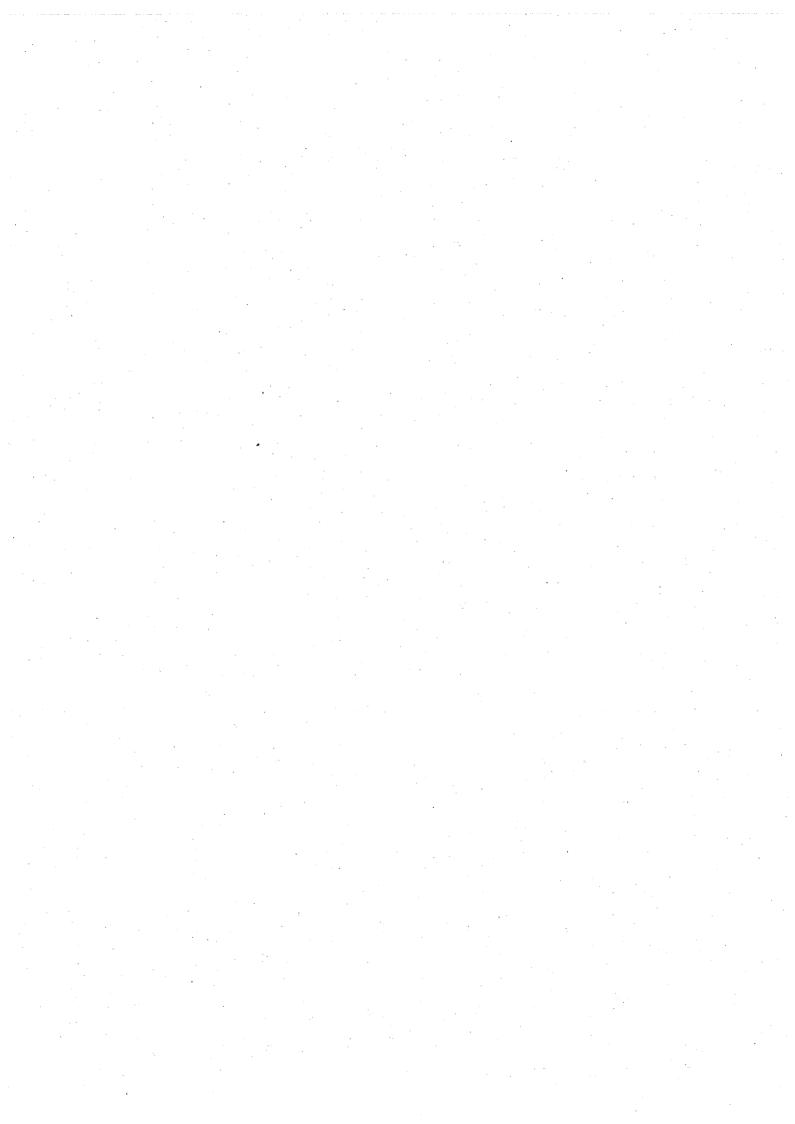
Page: 1 of 1

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.







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

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

Related Active ARTG Entry Information:

Manufacturer Evidence

Status: Versioned

		•	
Certificate change history	• .		

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:

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:

- O 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)

History of Quality Assurance Certificate

Certificate No:

CE 53820

Issue Date:

Issued to:

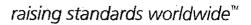
DePuy Spine

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.'

Page 3 of 3





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.

Page 2 of 3



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

Page 1 of 3



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	Sterilization
500 West 4th Street Lima	
OH 45804 USA	
RSI Leasing, Inc.	E beam Sterilization
dba Sterigenics 7695 Formula Place	
San Diego	
California 92121	

Page: 4 of 4





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:

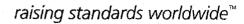
DePuy Spine

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			

Page: 3 of 4





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

SI	bco	nfra	ctor

Service(s) supplied

DePuy Spine 365 Ravendale Road Mountain View CA 94043 USA Manufacture

BeamOne LLC

Sterilization

9020 Activity Road, Suite D

San Diego CA 92126 USA

Isotron PLC

Sterilization

Marcus Close

Tilehurst Reading

Berkshire RG30 4EA United Kingdom

DePuy Inc.

Distribution

50 Scotland Park Drive Bridgewater Packaging Inspection

Massachusetts

USA 02324

Page: 2 of 4



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

Page: 1 of 4



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, 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):

First Issued: 4 Mar 2000

Date: 12 Apr 2011

Expiration Date: 3 Mar 2015

Page: 1 of 1

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.





#	Document Type	Description	Method
Relate	d Active ARTG Entry Info	rmation:	
	T		
1211	84 Depuy Australia	Pty Ltd - Prosthesis, internal, spine, disc	

History

Manufacturer Evidence

Status: Versioned

ert					

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:

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

Cartificate va issue data, (dd/mm/kunn)

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

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

Ethicon GmbH

Robert-Koch-Strasse 1

Norderstedt

Germany

22851

DePuy Spine SARL

Chemin Blanc 36

CH 2400 Le Locle

Switzerland

Isotron PLC

Marcus Close

Tilehurst

Reading

Berkshire

United Kingdom

RG30 4EA

DePuy Inc

50 Scotland Park Drive

Bridgewater

Massachusetts

USA

02324

Service(s) supplied

Sterilization

Manufacture

Sterilization

Distribution

Final Inspection

Packaging

Page: 2 of 3



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

Steris Corporation Isomedix Services 435 Whitney Street Northborough Massachusetts USA 01532

Kensey Nash Corporation 55 East Uwchlan Avenue Exton PA 19341 USA

Service(s) supplied

Sterilization

Animal substances

Page: 3 of 3



History of Quality Assurance Certificate

Certificate No:

CE 53820

Issue Date:

5 May 2005

Issued to:

DePuy Spine, Inc

Raynham

Date	Action
04 March 2000	Firstissue
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
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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.



