

EC Certificate - Full Quality Assurance System

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

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, spinal cement delivery systems, accessory needles and devices for stimulation and nerve mapping

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: **2000-03-04**

Date: **2021-05-21**

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

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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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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:

Certificate No: **CE 53820**
 Date: **2021-05-21**
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Subcontractor:	Service(s) supplied
3D Systems, Inc. 5381 South Alkire Circle Littleton Colorado 80127 USA	Manufacture
DePuy International Limited St Anthony's Road Leeds LS11 8DT United Kingdom	Manufacture
DePuy Ireland UC Loughbeg Ringaskiddy Co. Cork Ireland	EU Representative

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Subcontractor:	Service(s) supplied
DePuy Orthopaedics, Inc. 50 Scotland Blvd Bridgewater Massachusetts 02324 USA	Final Inspection Packaging
Isomedix Operations, Inc 435 Whitney Street Northborough Massachusetts 01532 USA	ETO Sterilization Radiation (Gamma Sterilization)
Kimball Electronics 2950 N. Catherwood Avenue Indianapolis Indiana 46219 USA	Manufacture

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Subcontractor:	Service(s) supplied
LayerWise NV (A 3DSystems Company) Grauwmeer 14 Heverlee 3001 Belgium	Manufacture
Lead-Lok Inc. 804 Airport Way Sandpoint Idaho 83864 USA	Manufacture
Medos Sarl Chemin Blanc 36 Le Locle CH-2400 Switzerland	Manufacture

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Subcontractor:	Service(s) supplied
Medos SARL Chemin Blanc 38 Le Locle CH-2400 Switzerland	Manufacture
Qualitel Corporation 11831 Beverly Park Road, Building A, Everett, Washington 98204 USA	Manufacture
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
steripac GmbH Oberreichenbacherstraße 15-17, 75365 Calw-Altburg Germany	Packaging Radiation (Gamma Sterilization)
Synergy Health Daniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland	Radiation (Gamma Sterilization)
Tegra Medical 8 Ledgewood Blvd. Dartmouth MA 02747 USA	Manufacture

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Date	Reference Number	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
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

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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 SARM to the list of significant subcontractors for manufacture. Addition of design activity for existing subcontractor DePuy Spine SARM. 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.
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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9 July 2012	7858280	Addition of 'Medos Sarl' as significant subcontractor for manufacture activities
21 August 2012	7880177	Sub-contractor company name change from " Leoni Studer AG, Studer Hard, 4658 Daniken, Switzerland " to " Synergy Health Daniken AG, 4658 Daniken, Switzerland" .
10 June 2014	8162293	Revision of scope, from 'The design, development and manufacture of spinal implant systems and instrumentation systems, bovine-derived bone graft material, spinal cement delivery systems and accessory needles' to 'The design, development and manufacture of spinal implant systems and instrumentation systems, spinal cement delivery systems and accessory needles'. Removal of – DePuy Spine, Ravendale Road, Mountain View, DePuy (Ireland), Isotron PLC at Marcus Close, Mediplast Israel Ltd, and Sor-Van Irradiation Ltd from list of significant subcontractor.

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02 March 2015	8283297	Certificate Renewal Removal of Subcontractors: <ul style="list-style-type: none"> • BeamOne LLC, San Diego • DePuy Spine Sarl, Le Locle • Kensey Nash Corp, Exton. • RSI leasing, Inc, San Diego • Synergy Health AST, LLC Lima. • DePuy, Inc, Bridgewater Addition of Subcontractors: <ul style="list-style-type: none"> • DePuy Orthopaedics, Inc. – For Inspection & Packaging • Medos Sarl – For Manufacture 'Manufacture' added as service for DePuy International
25 February 2019	7781005	Traceable to NB 0086.
13 January 2020	3095635	Certificate Renewal. Removal of subcontractor DePuy Motion Sarl. Minor correction to address of Synergy Health Daniken AG. Change of a name of STERIS Isomedix Services to Isomedix Operations, Inc.
24 April 2020	3152368	Extension of scope to include "devices for stimulation and nerve mapping" Addition of the following subcontractors for the activity of Manufacture; Lead-Lok Inc.; Kimball Electronics; Qualitel Corporation; Tegra Medical. Addition of Sterigenics US, LLC, Queensbury for the activity of ETO Sterilisation

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27 August 2020	3257149	Addition of the following subcontractors for the activity of Manufacture: LayerWise NV (A 3D Systems Company); 3D Systems, Inc. Addition of Steripac GmbH for the activities of Packaging and Gamma Sterilization.
Current	3443491	Change of EU Representative from DePuy International Limited to DePuy Ireland UC.