Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057034 0011 Rev. 01

Manufacturer:

Paradigm Spine GmbH
Eisenbahnstrasse 84
78573 Wurmlingen
GERMANY

Product Category(ies): **Spinal Implants, Trials and Instruments**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713160609

Valid from: 2020-04-08
Valid until: 2024-05-26

Date, 2020-04-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 52820**

Issued To: **Pioneer Surgical Technology Inc.**
375 River Park Circle
Marquette
Michigan
49855
USA

In respect of:

The design and manufacture of Porcine gelatin-based resorbable biological synthetic bone graft substitutes, sterile Hip fixation implants, non-sterile Orthopaedic bone screw and washer implants, sterile Orthopaedic fixation cerclage wire/cable implant, sterile and non-sterile Spinal fixation cable implant, sterile and non-sterile Sternal fixation cable/plate implants, non-sterile non-cervical Intervertebral spinal fusion implants, sterile Interbody fusion implants, sterile Interspinous lumbar decompression spacer implant and non-sterile instruments intended for connection to an active medical device and non-sterile single-use instruments.

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: **1999-11-29** Date: **2020-11-13** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 52820

Issued To:

Pioneer Surgical Technology Inc.
375 River Park Circle
Marquette
Michigan
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Number	Device Name	Intended purpose per IFU
Class III		
MD 0202 MDS 7009 MDS 7002	NanOss Bioactive Porcine Gelatin Resorbable Bone Void Filler	See CE 567423
MD 0202 MDS 7009 MDS 7002	NanoOss Bioactive 3D Bone Void Filler	See CE 651190
Class IIb		
61325	Bone-screw internal spinal fixation system	Intervertebral spinal fixation implant system, for non-cervical indications
60847	Spinal fusion cage	Interbody fusion implant
34017	Sternal Fixation system	Internal sternal fixation implant
61531	Lumbar Interspinous spacer	Interspinous decompression spacer implant for lumbar indications
61690	Hex Button	Internal orthopaedic fixation cerclage wire/cable implant
44797 61465	Spinal fixation cable system	Internal spinal cable fixation implant system
56642 61670	Orthopaedic bone screw and washer system	Orthopedic bone fixation implant system
34003	Hip internal fixation system (GTR-Great Trochanteric Reattachment)	Hip fixation implant
60847	3D printed PEKK interbody spinal fusion cages	Cervical Interbody Fusion, Lumbar Interbody Fusion, 1 or 2 contiguous levels for Spondylolisthesis or degenerative disc disease

First Issued: **1999-11-29** Date: **2020-11-13** Expiry Date: **2024-05-26**

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Supplementary Information to CE 52820

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Single-use orthopaedic instruments	Orthopedic manual surgical instrument, single use
MD 0106	Reusable instruments connect to an active device	Orthopaedic surgical instruments connected to active device, Reusable, Invasive (transient use)

First Issued: **1999-11-29** Date: **2020-11-13** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

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 52820**
Date:	**2020-11-13**
Issued To:	**Pioneer Surgical Technology Inc.** **375 River Park Circle** **Marquette** **Michigan** **49855** **USA**

Subcontractor:	**Service(s) supplied**
Boston Centerless Inc. 11 Presidential Way Woburn Massachusetts 01801 USA	**Crucial Supplier**
Fort Wayne Metals Research Products Corporation 9609 Ardmore Avenue Fort Wayne Indiana 46809 USA	**Crucial Supplier**
Gelita USA, Inc. 2445 Port Neal Industrial Road Sergeant Bluff IA 51054 USA	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System

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Subcontractor:	**Service(s) supplied**
Himed 148 Sweet Hollow Road Old Bethpage New York 11804 USA	**Crucial Supplier**
Invibio Ltd Invibio Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom	**Crucial Supplier**
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**

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

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Gamma Irradiation**
Lowell, Inc. 9425 83rd Avenue North Minneapolis Minnesota 55445 USA	**Crucial Supplier**
Oxford Performance Materials, Inc. 30 South Satellite Road South Windsor CT 06074 USA	**Manufacture**

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

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Subcontractor:	**Service(s) supplied**
Pioneer Surgical Technology Inc. 1800 A North Greene St. Greenville North Carolina 27834 USA	**Design** **Development** **Final Inspection** **Manufacture** **Packaging**
Titanium Industries 18 Green Pond Road Rockaway New Jersey 07866 USA	**Crucial Supplier**
Tutogen Medical GmbH (an RTI Surgical, Inc. company) Industriestrasse 6 91077 Neunkirchen am Brand Germany	**EU Representative**

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List of Significant Subcontractors

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Issued To:	**Pioneer Surgical Technology Inc.** **375 River Park Circle** **Marquette** **Michigan** **49855** **USA**

Subcontractor:	**Service(s) supplied**
Veridiam 1717 North Cuyamaca St. El Cajon California 92020 USA	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 52820**
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Date	Reference Number	Action
29 November 1999	-	First Issued.
21 July 2000	-	Added "sterile" to the scope.
7 June 2001	-	Revised wording of the scope.
26 April 2004	-	Addition of sterilization subcontractor and certificate renewal.
25 July 2005	-	Extension to scope to include spinal arthroplasty devices.
22 June 2009	7215069	Clarification of scope. Addition of 'RSQR Ltd' as subcontractor for EU Representative Certificate Renewal.
04 March 2011	7633143	Addition of ETO Sterilization subcontractor STERIS Isomedix Services at Spartanburg, and Pioneer Surgical Greenville and Woburn sites.
28 February 2012	7780845	Scope extension to cover, 'resorbable biological synthetic bone graft substitutes'. Addition of significant subcontractor, a HA coating provider, Eurocoating S.p.A., Valsugana, for Other Critical Processes.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
17 June 2014	8179925	Certificate Renewal. Added 'instruments intended for connection to an active medical device' to the certificate scope. Added Pioneer Surgical Technology, Austin TX, to the list of significant subcontractors. Removed Pioneer Surgical Technology, Woburn MA, from the list of significant subcontractors.

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
22 February 2017	8631197	Scope clarification to better identify product composition and intended use of instruments. Extension of activities for subcontractor "Pioneer Surgical Technology Inc.", to include Packaging and Final Inspection. Small amendment to EU Representative address from "RSQR Ltd., Ludgate House, 107-111 Fleet Street, London, EC4A 2AB, United Kingdom" to "RSQR Ltd., Ludgate House, 107 Fleet Street, London, EC4A 2AB, United Kingdom", for consistency. Critical subcontractor name amendment from "STERIS Isomedix Services, Inc." to "Steris Isomedix Services". Addition of Crucial Suppliers "Banner Medical Corp., 494 East Lies Road, Carol Stream, Illinois 60188, USA"; "Forecreu, 3735 West Belmont Ave., Chicago, Illinois 60618, USA"; "Fort Wayne Metals, 9609 Indianapolis Road, Fort Wayne, Indiana 46899, USA"; "Invibio Ltd, Invibio Technology Centre, Hillhouse International, Thornton-Cleveleys, Lancashire, FY5 4QD, United Kingdom"; "FSSB, Chirurgische Nadeln GmbH Allmendweg 2, 79798 Jestetten, Germany"; "Veridiam, 1717 North Cuyamaca St., El Cajon, California, 92020, USA"; "Gelita USA, Inc., 2445 Port Neal Industrial Road, Sergeant Bluff, IA 51054, USA"; "Himed, 148 Sweet Hollow Road, Old Bethpage, NY 11804, USA" and "Sigma-Aldrich, 3050 Spruce St, St. Louis, MO 63103, USA". Correction of typo in history page, to correct first issue date.

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2020-11-13**
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Date	Reference Number	Action
05 February 2019	7781001	Traceable to NB 0086.
08 May 2019	9720297	Change of EU Representative from "RSQR Ltd" to" Tutogen Medical GmbH (an RTI Surgical, Inc. company), Industriestrasse 6, 91077 Neunkirchen am Brand, Germany". Removal of critical subcontractor "Steris Isomedix Services, 2072 Southport Road, Spartanburg, South Carolina, 29306, USA" for the activity of ETO Sterilization. Removal of critical subcontractor "Pioneer Surgical Technology, Inc., 9600 Great Hills Trail, Suite 160E, Austin, Texas, 78759, USA" for the activity of Design & Development. Removal of crucial supplier "Forecreu". Addition of crucial suppliers "Boston Centerless Inc., 11 Presidential Way, Woburn, Massachusetts, 01801, USA"; "Titanium Industries, Inc., 18 Green Pond Road, Rockaway, New Jersey, 07866, USA"; "Barber of Sheffield, Unit 25 Shortwood Court, Shortwood Business Park, Dearne Valley Parkway, Barnsley, S74 9LH, United Kingdom"; "Lowell Inc., 9425 83rd Avenue North, Brooklyn Park, Minnesota, 55445, USA"; and "Structure Medical, 505 Production Avenue, Madison, Alabama, 35758, USA";

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Date	Reference Number	Action
18 June 2019	9686118	Certificate Renewal. Clarification of scope to confirm the specific device families under certification. Crucial Supplier name update from "Fort Wayne Metals" to "Fort Wayne Metals Research Products Corporation"; Critical Subcontractor name update from "Steris Isomedix Services" (1880 Industrial Drive) to "Isomedix Operations, Inc., North Facility" and "Steris Isomedix Services" (2500 Commerce Drive) to "Isomedix Operations, Inc.". Critical Subcontractor address update for "Eurocoating S.p.A.". Crucial Supplier address update for "Fort Wayne Metals Research Products Corporation" and "Lowell, Inc.".
Current	3269341	Extension to scope to include "3D printed PEKK interbody spinal fusion cages" Additon of "Oxford Performance Materials, Inc." as critical subcontractor for manufacture. Removal of critical supplier "Eurocoating S,p,A" for the function of "Other Critical Processes" Removal of crucial suppliers "Banner Medical Corp", "FSSB", "Sigma-Aldrich corporation", "Baber of Sheffield" and "Structure Medical"