

EC Certificate - Full Quality Assurance System

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

No. CE 96026
Issued To: NuVasive, Inc.
7475 Lusk Blvd.
San Diego
California
92121
USA

In respect of:

The design and manufacture of sterile and non-sterile neurophysiologic guidance systems, electrodes, image processing software, spinal internal fixation systems, spinal stabilization, mechanical / articulating total disc replacement implants for the lumbar and cervical spine, surgical meshes and associated surgical single-use accessories and instrument kits for spinal surgery.
Those aspects of Annex II related to securing and maintaining sterile conditions in the design and manufacture of instruments used during spinal procedures.

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: **2005-05-13**

Date: **2020-09-08**

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.

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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 96026**
Date: **2020-09-08**
Issued To: **NuVasive, Inc.**
7475 Lusk Blvd.
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Subcontractor:	Service(s) supplied
3D Systems, Inc 5381 South Alkire Circle Littleton Colorado 80127 USA	Manufacture
ARCH Medical & Aerospace 8740 49th Avenue North New Hope, MN 55428 USA	Manufacture
Avalign-Instruments & Implants 8727 Clinton Park Drive Fort Wayne Indiana 46825 USA	Manufacture

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Subcontractor:	Service(s) supplied
Boston EndoSurgical Technologies, a division of Lacey Manufacturing Company LLC. 1146 Barnum Avenue Bridgeport Connecticut 06610 USA	Manufacture Packaging
Centurion Medical Products Corporation 301 Catrell Drive Howell Michigan 48843 USA	ETO Sterilization
Cousin Biotech s.a.s. 8, Rue de l'Abbé Bonpain 59117 Wervicq-Sud France	Manufacture

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Subcontractor:	Service(s) supplied
Culver Tool & Engineering Inc. 1901 Walter Glaub Drive Plymouth Indiana 46563 USA	Manufacture
Engineered Medical Systems, LLC 3325 Appling Road, Bartlett Tennessee 38133 USA	Manufacture
FMI Medisch B.V. De Brauwweg 17 Schiedam 3125 AE Netherlands	Manufacture

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Subcontractor:	Service(s) supplied
Guardian Medical USA, LLC 11360 S Airfield Rd Swanton Ohio 43558 USA	Packaging
Hoosier 1152 California Avenue Corona California 92881 USA	Manufacture
Insert Molding Solutions Inc. 4325 Settingdown Circle, Suite 103 Cumming Georgia 30028 USA	Manufacture Packaging

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Isomedix Operations, Inc 435 Whitney Street Northborough Massachusetts 01532 USA	Gamma Irradiation
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	Gamma Irradiation
Isomedix Operations, Inc. 4405 Marketing Place Groveport, Ohio 43125 USA	Gamma Irradiation

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Jade Precision Medical Components 3063-B Philmont Avenue Huntingdon Valley Pennsylvania 19006 USA	Manufacture
Life Science Outsourcing, Inc. 830 Challenger Street Brea California 92821 USA	Manufacture Packaging
Microcision, LLC also DBA Aeton Medical LLC 7115 Airport Hwy Pennsauken, New Jersey 08109 USA	Manufacture

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Millstone Medical Outsourcing LLC 580 Commerce Dr. Fall River MA 02720 USA	Packaging
NN Life Sciences - Hatfield 2342 North Penn Road Hatfield Pennsylvania 19440 USA	Manufacture
NN, Inc. Precision Engineered Products Group, Vandalia 4201 Little York Rd. Dayton OH 45414 USA	Manufacture

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Northern Digital, Inc. 103 Randall Drive Waterloo Ontario N2V 1C5 Canada	Manufacture
NuVasive Netherlands B.V. Jachthavenweg 109A 1081 KM Amsterdam The Netherlands	EU Representative
NuVasive, Inc. 805 Liberty Lane West Carrollton Ohio 45449 USA	Final Inspection Manufacture

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NuVasive, Inc. 4670 E. Shelby Drive, Building B Memphis Tennessee 38118 USA	Manufacture
Oerlikon AM Medical Inc. 10 Constitution Boulevard South Shelton Connecticut 06484 USA	Manufacture
ONYX Healthcare Inc. 2F, No.135, Lane 235 Pao Chaio Rd. Hsin-Tien Dist., New Taipei City 231 Taiwan	Design Manufacture

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Orchid Anzon Orthopedic Solutions 11911 Clark Street Arcadia California 91006 USA	Manufacture
Orchid Orthopedics Switzerland GmbH Täferenstrasse 39 5405 Baden-Dättwil AG Switzerland	Manufacture
P1 Technologies Inc. 6591 Merriman Road Roanoke Virginia 24018 USA	Manufacture

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Parter Sterilization Services A Division of Parter Medical Products 17115 Kingsview Avenue Carson CA 90746 USA	ETO Sterilization
Pulse Technologies 2000 AM Dr Quakertown Pennsylvania 18951 USA	Manufacture
Quality Tech Services Inc. 10525 Hampshire Avenue Bloomington Minnesota 55438 USA	Packaging

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Remington Medical, Inc 6830 Meadowridge Court Alpharetta Georgia 30005 USA	Manufacture Packaging
rms Company 8600 Evergreen Boulevard Minneapolis Minnesota 55433 USA	Manufacture
SELENIUM MEDICAL 40 Rue de chef de Baie ZI de Chef de Baie 17000 LA ROCHELLE France	Gamma Irradiation

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Subcontractor:	Service(s) supplied
Sparton Medical Systems Colorado, LLC 4300 Godding Hollow Parkway Frederick Colorado 80540 USA	Manufacture
Structure Medical LLC 9935 Business Circle Naples Florida 34112 USA	Manufacture
Tecomet, Inc. 115 Eames Street Wilmington Massachusetts 01887 USA	Manufacture

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Tomz Corporation 47 Episcopal Rd. Berlin Connecticut 06037 USA	Manufacture
Turner Medical Inc. dba In'Tech America 130 Durham Drive Athens AL 35611 USA	Manufacture
Ultra Machining Company (UMC) 500 Chelsea Road Monticello Minnesota 55362 USA	Manufacture

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Date	Reference Number	Action
13 May 2005	-	First Issue – NB Transfer
17 December 2008	7046790	Change of scope Addition of Isotron PLC to the list of significant subcontractors for gamma sterilization Addition of Kirwan, Microcision, Nemcomed Ohio, Nemcomed Indiana, OMC Precision Products, Pearsalls Ltd, Pulse Technologies, Remington Medical, Structure Medical, and United Orthopedic Corporation to the list of significant subcontractors for manufacture Removal of Riley Medical from the list of significant subcontractors
30 November 2009	7458323	Scope extension to include mechanical / articulating disc prosthesis for the lumbar and cervical spine Addition of subcontractors: Orchid Biocoat, Remington Medical Inc., DOT GmbH, BGS Beta-Gamma-Service GmbH & Co KG, Waldemar Link GmbH & Co., NuVasive UK Ltd., C5 Medical Werks Inc. and DRT Manufacturing
22 April 2010	7465380	Certificate Renewal. Removal of significant subcontractor: United Orthopedic Corporation. Company name change from Anzon Company, Inc. to Orchid Anzon Orthopedic Solutions.
04 March 2011	7458323	Extension of scope to include 'surgical meshes' Change to two Remington Medical, Inc. subcontractors to combine activities into a single subcontractor

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Date	Reference Number	Action
		Addition of subcontractors: <ul style="list-style-type: none"> • Orchid Anzon Company, ElMonte, CA – Manufacture • ANC, Fairborn, OH – Final Inspection, Manufacture • Astro Medical Devices, Mentor, OH – Final Inspection, Manufacture • Boston Endo-Surgical Technologies, Inc, Hampton, OH – Manufacture • Culver Tools BV, Plymouth, IN – Final Inspection, Manufacture • Hoosier, Corona, CA - Final Inspection, Manufacture • Jade Precision Medical Components, Southampton, PA - Final Inspection, Manufacture • Lisi Jeropa, Escondido, CA - Final Inspection, Manufacture • Millstone Medical Outsourcing, Fall River, MA – Packaging • Sandvik Medical Solutions (TN), Memphis, TN - Final Inspection, Manufacture • Sandvik Medical Solutions (UK), Sheffield, South Yorkshire - Final Inspection, Manufacture • Sandvik Medical Solutions (CT), Milford, CT - Final Inspection, Manufacture • Norman Noble Inc, Highland Heights, OH – Manufacture • Gamma Service, Radeberg, DE – Gamma Sterilisation

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		Removal of subcontractor, Nemcomed, Hicksville, OH – Manufacture Correction of address, NuVasive UK Ltd, 'WD6 3SN' to 'WD6 3FG'
18 August 2011	7709028	Change to scope to include Annex V Section 3.2 certificate CE 544318: From - "The design and manufacture of sterile and non-sterile neurophysiologic guidance systems, electrodes, spinal internal fixation systems, mechanical / articulating disc prosthesis for the lumbar and cervical spine, surgical meshes and associated surgical single-use accessories." To - "The design and manufacture of sterile and non-sterile neurophysiologic guidance systems, electrodes, spinal internal fixation systems, spinal stabilization, mechanical / articulating total disc replacement implants for the lumbar and cervical spine, surgical meshes, associated surgical single-use accessories and instrument kits for spinal surgery. Those aspects of Annex II related to securing and maintaining sterile conditions of instruments used during spinal procedures." Change to significant subcontractor's name and address from 'Delphi Medical Systems Corporation, 4300 Road 18, Longmont, CO 80504, USA' to 'Sparton Medical Systems Colorado LLC, 4300 Godding Hollow Parkway, Frederick, Colorado 80504, USA'

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		Change to significant subcontractor's name and address from 'DRT Manufacturing, 618 Greenmount Blvd, Dayton, Ohio 45419, USA' to 'Tipp Machine & Tool Inc., 4201 Little York Road, Dayton, Ohio, 45414 USA' Addition of significant subcontractors: <ul style="list-style-type: none"> • Aaeon Technology Inc., Hsin-Tien City, Taipei Hsien for Other Significant Activities (Servicing) • Bob, Inc., New Hope, MN for Manufacturing Activities • FMI Medisch B.V., Schiedam, The Netherlands for Manufacturing activities • Insert Molding Solutions Inc., Cumming, Georgia for Manufacture and Packaging activities • Turner Medical Inc., Athens, Alabama for Manufacture activities • NuVasive, Inc. Memphis, Tennessee for Manufacture activities
3 July 2012	7816385	Addition of Significant subcontractors: <ul style="list-style-type: none"> • Plastics One Inc, Roanoke, Virginia for Manufacture activities. • DRT Medical, LLC, Dayton, Ohio for Manufacture activities • Orchid Orthopedic Solutions, Sheffield, South Yorkshire for Manufacture activities • Orchid Orthopedic Solutions, Centre of Excellence, Sheffield for Manufacture activities

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		<ul style="list-style-type: none"> • ONYX Healthcare Inc, New Taipei City, Taiwan for Design and Manufacture activities • Orchid Orthopedic Solutions, Alabama for Manufacture activities <p>Removal of Significant Subcontractors:</p> <ul style="list-style-type: none"> • Luxtec Corporation, West Boylston, Massachusetts for Manufacture activities • OMC Precision, Indianapolis, Indiana for Manufacture activities • C5 Medical Werks Inc., Grand Junction, Colorado for Manufacture activities • Sandvik Medical Solutions (TN), Memphis Tennessee, for Final Inspection and Manufacture activities • Sandvik Medical Solutions (UK), Sheffield, UK for Final Inspection and Manufacture activities • Aaeon Technology Inc., Hsin-Tien City, Taipei for Other Critical Processes activities <p>Change to significant subcontractor's name from Sadnvik Medical Solutions (CT) to Orchid Orthopedic Solution</p> <p>Change to significant subcontractor's address for Boston Endo-Surgical Technologies Inc. from '8 Merrill Industrial Drive, Hampton, OH 03842, USA' to '1146 Barnum Avenue, Bridgeport, CT 06610, USA'</p>

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19 June 2015	8346477	<p>Certificate Renewal</p> <p>Removal of Significant subcontractors:</p> <p>'Norman Noble Inc.', 'Isotron Ltd., Waldemar Link GmbH & Co', 'Pearsalls Limited', 'Lisi Medical Jeropa Inc.', "BGS Beat-Gamma Service GmbH & Co KG", "Orchid Biocoat" & "Orchid Orthopedic Solutions" at City Park Drive location and Parkway Close location.</p> <p>Correction of address for significant subcontractors:</p> <ul style="list-style-type: none"> 'Jade Precision Medical Components' from '105A James Way, Southampton, PA 18966, USA' to '3063-B Philmont Avenue, Huntingdon Valley, PA 19006, USA' 'DRT Medical LLC' from '818 Greenmount Avenue' to '618 Greenmount Blvd' 'Structure Medical LLC' from '2975 South Horseshoe Drive, Naples, Florida, 34104, USA' to '9935 Business Circle, Naples, Florida 34112, USA' Address clarification of FMI Medisch B.V. to 'De Brauwweg 17, Schiedam 3125 AE, Netherlands' Orchid Anzon Orthopedic solutions, 11911 Clark St., Arcadia, CA 91006, USA <p>Change of significant subcontractor trading names:</p> <ul style="list-style-type: none"> From 'Boston Endo Surgical Technologies' to 'Lacey Manufacturing Co, LLC'

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Date	Reference Number	Action
		<ul style="list-style-type: none"> • From 'Gamma Service' to 'Synergy Health Radeburg GmbH' • From 'Tipp Machine & Tool Inc. ' to 'DRT Medical LLC' • ANC at 1 Herald Square is now NML, the address and activity remain unchanged. <p>Addition of Significant Subcontractors:</p> <ul style="list-style-type: none"> • 'Southeastern Technology Inc. 905 Industrial Drive, Murfreesboro, TN 37129, USA' for the activity Manufacture • 'Aeromed, 2342 North Penn road, Hatfield, PA 19440, USA' for the activity Manufacture • 'Ultra Machining Company (UMC), 500 Chelsea Road, Monticello, MN 55362, USA' for the activity Manufacture • 'Surface Dynamics LLC, 231 Northland Blvd, Cincinnati, Ohio, 45246, USA' for the activity Manufacture • 'Quality Tech Services Inc. , 10525 Hampshire Avenue, Bloomington, Minnesota, 55438, USA' Activity: Packaging <p>Other changes to the certificate are:</p> <ul style="list-style-type: none"> • Remove activity of final inspection for Astro Medical Devices • Remove activity of microbiology service for Centurion Sterilization Services • Remove activity of final inspection for Culver Tools BV • Addition of packaging as an activity for DOT GmbH

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		<ul style="list-style-type: none"> • Remove activity of final inspection for Hoosier • Addition of packaging as an activity for Lacey Manufacturing Co, LLC • Remove activity of control of sterilization and add packaging activity for Life Science Outsourcing, Inc. • Remove activity of final inspection for Orchid Orthopedic Solutions at Raton Dr. • Remove activity of labelling for Remington Medical, Inc.
21 February 2019	7781017	Traceable to NB 0086.
27 May 2020	3067985	Renewal of Certificate with Scope change: To add 'image processing software' to the existing scope. Subcontractor Additions: <ul style="list-style-type: none"> •3D Systems •Cousin Biotech S.A.S. •Guardian Medical USA, LLC •Isomedix Operations, Inc. (2 new sites-4405 Marketing Place, Groveport, Ohio 43125 USA & 435 Whitney Street, Northborough, Massachusetts 01532 USA) •Northern Digital, Inc. •NuVasive, Inc. - Addition of West Carrollton, Ohio, USA facility

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		<ul style="list-style-type: none"> •Oerlikon AM Medical Inc. •Parter Sterilization Services •Selenium Medical •Tomz Corporation Subcontractor Removals: •Astro Medical Devices •DOT GmbH •DRT Medical •Kirwan •Nelson Laboratories •NML •Orchid Orthopedic Solutions •Southeastern Technology Inc. •Surface Dynamics •Synergy Health Radeberg GmbH Subcontractor Modifications •AeroMed – Name change to AeroMed to NN Life Science – Hatfield •Bob, Inc.– Name change to BOB Manufacturing LLC •Centurion Sterilization Services (Tri-State Hospital Supply

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Date	Reference Number	Action
		Corp.) - Name change to Centurion Medical Products Corporation •Culver Tools BV - Name change to Culver Tool & Engineering Inc. •DRT Medical LLC - Name change to NN, Inc. Precision Engineered Products Group, Vandalia •FMI Medisch B.V. country name from 'The Netherlands' to 'Netherlands'. •Hoosier - Added state name 'California' •Lacey, Inc. - Name change to Boston EndoSurgical Technologies, a division of Lacey Manufacturing Company LLC. •Microcision - Name change to Microcision, LLC also DBA Aeton Medical, LLC •Nemcomed - Name change to Avalign-Instruments & Implants •RMS Company name update to match with ISO 13485 certificate to rms Company, and also correction to its zip/postal code •Steris Corporation Isomedix Services – Name change to Isomedix Operations, Inc.

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		<ul style="list-style-type: none"> •Turner Medical Inc. - Name change to Turner Medical Inc. dba In'Tech America. EU Representative changed from NuVasive UK Ltd. to NuVasive Netherlands B.V.
08 July 2020	9732593	Addition of subcontractors - Ochid Orthopedics Switzerland GmbH & Tecomet, Inc.
Current	3278740	Subcontractor updates: "Plastics One" – Name change to "P1 Technologies Inc." & "BOB Manufacturing LLC" – Name change to "ARCH Medical & Aerospace – Minneapolis, LLC.".

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

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