

Đại sứ quán nước CHXHCN Việt Nam tại Hoa Kỳ Embassy of the S.R of Vietnam in the United States of America

CHỨNG NHẬN/HỢP PHÁP HÓA LẪNH SỰ CONSULAR AUTHENTICATION

1. Quốc gia Country

Việt Nam Vietnam

Giấy tờ, tài liệu này This public document

2. do Ông/Bà

JOHN C. WOBENSMITH

ký

has been signed by 3. với chức danh:

BÔ TRƯỞNG NGOẠI GIAO

acting in the capacity of 4. và con dấu của

Secretary of State **BANG MARYLAND** State of MARYLAND

bears the seal/stamp of

được chứng nhận/hợp pháp hóa lãnh sự Certified

5. tại Washington D.C, Hoa Kỳ

6. ngày 26 tháng 03 năm 2021

at Washington D.C

the (dd/mm/yy)

- 7. Cơ quan cấp: Đại sứ quán nước CHXHCN Việt Nam tại Hoa Kỳ By Embassy of the S.R of Vietnam in the United States of America
- 8. Số/No. 578/HPH/2021

TL. Đại sứ/ For the Ambassador

ham tan Counsellor

QUANG MINH

BANG MARYLAND

Văn phòng Bộ trưởng Ngoại giao

Tôi, John C. Wobensmith, Bộ trưởng Ngoại giao Bang Maryland, căn cứ quyền hạn và chức năng của tôi tại Điều 7-106 Mục về Chính quyền Bang Bộ Luật sửa đổi Maryland, chứng nhận rằng

SCOTT A. POYER

người làm và ký tên trên giấy chứng nhận kèm theo, tại thời điểm này, đã được bổ nhiệm và đủ tiêu chuẩn làm Lục sự Tòa lưu động và các việc làm chính thức của người này cần được tin tưởng tại mọi Toà án và ở mọi nơi.

Để xác nhận, tôi ký tên và đóng dấu chính thức của Bộ trưởng Ngoại giao, tại Annapolis, ngày 19/03/2021.

(Đã ký và đóng dấu) Bộ trưởng Ngoại giao.

Chứng thực ông Nguyễn Duy Khiêm, Bí thư thứ Nhất, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, đã ký trước mặt tôi.

Tôi, Nguyễn Duy Khiêm, Bí thư thứ Nhất, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, cam đoan đã dịch chính xác văn bản này từ tiếng Anh sang tiếng Việt.

Ngày 26 tháng 03 năm 2021

TL Đại sứ

Nguyễn Quang Minh

Ngày 26 tháng 03 năm 2021 Người dịch

Nguyễn Duy Khiêm

BANG MARYLAND, Quận ANNE ARUNDEL

VĂN PHÒNG LỤC SỰ TÒA LƯU ĐỘNG QUẬN ANNE ARUNDEL

Tôi, SCOTT A. POYER, Lục sự Tòa lưu động Quận ANNE ARUNDEL, Bang MARYLAND, đồng thời là Tòa lưu giữ hồ sơ, xác nhận rằng AHMAD MISKI được bổ nhiệm làm công chứng viên bắt đầu từ ngày 01/05/2017.

Để xác nhận, tôi ký tên và đóng dấu chính thức của Tòa Lưu động Quận ANNE ARUNDEL, Bang Maryland ngày 19/03/2021.

(Đã ký và đóng dấu) SCOTT A. POYER Lục sự Tòa lưu động Quận ANNE ARUNDEL, Maryland.

Chứng thực ông Nguyễn Duy Khiêm, Bí thư thứ Nhất, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, đã ký trước mặt tôi. Tôi, Nguyễn Duy Khiêm, Bí thư thứ Nhất, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, cam đoan đã dịch chính xác văn bản này từ tiếng Anh sang tiếng Việt.

Ngày 26 tháng 03 năm 2021

TL Đại sứ

VI ham ton

Nguyễn Quàng Minh

Ngày 26 tháng 03 năm 2021 Người dịch

Nguyễn Duy Khiêm

NA WHOOL



The State of Maryland

Office of the Secretary of State

This Certification is not valid for use anywhere within the United States of America, its territories or possessions.

This Certification does not certify the content of the document for which it is issued.

I, John C. Wobensmith, Secretary of State of Maryland, under and by virtue of the authority vested in me by Section 7-106 of the State Government Article of the Annotated Code of Maryland, Do Hereby Certify that

Scott A. Poyer

who has made and signed the attached certificate, was on the date thereof, the duly elected and qualified Clerk of the Circuit Court whose official acts as such should be given full faith and credit in all Courts of Justice and elsewhere.



In Testimony Whereof, I hereunto set my hand and have caused to be affixed the official seal of of the Secretary of State, at Annapolis, this 19th day of March, in the year of our Lord 2021

Secretary of State

John C. Wohenste

No. 303181

bsi.



EC Certificate - Full Quality Assurance System

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

No.

Issued To:

CE 96026

NuVasive, Inc. 7475 Lusk Blvd. San Diego California 92121 USA I, Hanadi Ajami, hereby certify that this this document is a true copy of the original

State of Maryland, Anne Aundel Count Subscribed and Swom to before me by Hamedi Ajami.

Ahmad Miski Notary Public

My Commission expines on May 26, 20



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

240587

State of Maryland, Anne Arundel County, Sct.

I, SCOTT A. POYER, Clerk of the Circuit Court for Anne Arundel County, Maryland, a court of record, do hereby certify that **Ahmad Miski** was a commissioned/appointed and qualified Notary Public commencing on the 1st day of May, 2017.

In Testimony Whereof, I have hereunto set my hand and affixed the seal of the court March 19, 2021

Scott A. Poyer

Scott A. Poyer, Clerk

Circuit Court for Anne Arundel County, Maryland





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

Gary C Stade

First Issued: 2005-05-13 Date: 2020-09-08 Expiry Date: 2024-05-26

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Page 1 of 1

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.





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. San Diego California 92121 USA

Subcontractor: Service(s) supplied

3D Systems, Inc 5381 South Alkire Circle Littleton Colorado 80127 Manufacture

ARCH Medical & Aerospace 8740 49th Avenue North New Hope, MN

55428 USA

USA

Manufacture

Avalign-Instruments & Implants 8727 Clinton Park Drive Fort Wayne Indiana

46825 USA **Manufacture**

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Page 1 of 14





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.

San Diego California

92121 USA

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

Cousin Biotech s.a.s. 8, Rue de l'Abbé Bonpain

59117 Wervicq-Sud

France

ETO Sterilization

Manufacture

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Page 2 of 14





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.

San Diego California 92121 USA

Subcontractor:

Service(s) supplied

Culver Tool & Engineering Inc. 1901 Walter Glaub Drive Plymouth **Manufacture**

Plymouth Indiana 46563 USA

Engineered Medical Systems, LLC

Manufacture

3325 Appling Road, Bartlett

Bartlett Tennessee 38133 USA

FMI Medisch B.V. De Brauwweg 17

De Brauwweg 1 Schiedam

3125 AE

Netherlands

Manufacture

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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. San Diego

California 92121

USA

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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Page 4 of 14





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. San Diego California 92121 USA

Subcontractor:

USA

91761 USA

USA

Service(s) supplied

Isomedix Operations, Inc 435 Whitney Street Northborough Massachusetts 01532

Gamma Irradiation

Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California

Gamma Irradiation

Isomedix Operations, Inc. 4405 Marketing Place Groveport, Ohio

43125

Gamma Irradiation

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Page 5 of 14





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. San Diego

California 92121 USA

Subcontractor:

Service(s) supplied

Jade Precision Medical Components 3063-B Philmont Avenue Huntingdon Valley Pennsylvania 19006 USA Manufacture

Life Science Outsourcing, Inc. 830 Challenger Street Brea Manufacture Packaging

California 92821 USA

USA

Microcision, LLC also DBA Aeton Medical LLC 7115 Airport Hwy Pennsauken, New Jersey 08109 **Manufacture**

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Page 6 of 14





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.

San Diego California 92121 USA

Subcontractor:

Service(s) supplied

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 **Manufacture** 4201 Little York Rd.

Dayton

ОН

45414

UŞA

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Page 7 of 14





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.

San Diego

California

92121 **USA**

Subcontractor:

Service(s) supplied

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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Page 8 of 14





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. San Diego California 92121

USA

Subcontractor:

Service(s) supplied

NuVasive, Inc.

4670 E. Shelby Drive, Building B

Memphis

Tennessee 38118

USA

Manufacture

Manufacture

Oerlikon AM Medical Inc.

10 Constitution Boulevard South

Shelton Connecticut 06484

USA

Design

2F, No.135, Lane 235

ONYX Healthcare Inc.

Pao Chaio Rd.

Hsin-Tien Dist., New Taipei City

231

Taiwan

Manufacture

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Page 9 of 14





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. San Diego California

92121 **USA**

Subcontractor:

Service(s) supplied

Orchid Anzon Orthopedic Solutions

11911 Clark Street

Arcadia

California

91006 **USA**

Manufacture

Orchid Orthopedics Switzerland GmbH

Täfernstrasse 39

5405 Baden-Dättwil AG

Switzerland

Manufacture

P1 Technologies Inc. 6591 Merriman Road

Roanoke

Virginia

24018 **USA**

Manufacture

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Page 10 of 14





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.

San Diego California 92121

USA

Subcontractor:

Service(s) supplied ETO Sterilization

Parter Sterilization Services

A Division of Parter Medical

A Division of Parter Medical Products

17115 Kingsview Avenue

Carson CA

90746

USA

W. J. J.

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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Page 11 of 14





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. San Diego California

92121 USA

 _	
 L	 ctor:
 ~~~	 ~~~

Service(s) supplied

Remington Medical, Inc 6830 Meadowridge Court Manufacture Packaging

Alpharetta Georgia 30005

USA

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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Page 12 of 14





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.

San Diego California

92121 **USA** 

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 Earnes Street Wilmington Massachusetts 01887 **USA** 

Manufacture

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Page 13 of 14





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.

San Diego California 92121 USA

#### **Subcontractor:**

Service(s) supplied

Tomz Corporation 47 Episcopal Rd.

Manufacture

Berlin Connecticut 06037 USA

Turner Medical Inc. dba In Tech America

Manufacture

130 Durham Drive

Athens AL 35611 USA

Ultra Machining Company (UMC)

Manufacture

500 Chelsea Road Monticello Minnesota

55362

USA

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Page 14 of 14





Certificate No:

**CE 96026** 

Date:

2020-09-08

Issued To:

NuVasive, Inc. 7475 Lusk Blvd.

San Diego California 92121 USA

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 subcontrators: 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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Page 1 of 11

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.





Certificate No:

**CE 96026** 

Date:

2020-09-08

Issued To:

NuVasive, Inc.

7475 Lusk Blvd. San Diego

California 92121 **USA** 

Date	Reference Number	Action
		Addition of subcontractors:
		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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Certificate No:

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Date:

2020-09-08

Issued To:

NuVasive, Inc.

7475 Lusk Blvd. San Diego California 92121 USA

Date	Reference Number	Action
		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 tota 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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Page 3 of 11

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Date:

2020-09-08

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NuVasive, Inc. 7475 Lusk Blvd.

San Diego California 92121 USA

Date	Reference Number	Action
		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> <li>Aaeon Technology Inc., Hsin-Tien City, Taipei Hsien for Other Significant Activities (Servicing)</li> </ul>
		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:
		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
		<ul> <li>Orchid Orthopedic Solutions, Centre of Excellence, Sheffield for Manufacture activities</li> </ul>

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Page 4 of 11

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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2020-09-08

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NuVasive, Inc.

7475 Lusk Blvd. San Diego California 92121 USA

Date	Reference Number	Action	
		ONYX Healthcare Inc, New Taipei City, Taiwan for Design and Manufacture activities	
		Orchid Orthopedic Solutions, Alabama for Manufacture activities	
		Removal of Significant Subcontractors:	
		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	
		<ul> <li>Sandvik Medical Solutions (TN), Memphis Tennessee, for Fina Inspection and Manufacture activities</li> </ul>	
		Sandvik Medical Solutions (UK), Sheffield, UK for Final Inspection and Manufacture activities	
		<ul> <li>Aaeon Technology Inc., Hsin-Tien City, Taipei for Other Critica Processes activities</li> </ul>	
		Change to significant subcontractor's name from Sadnvik Medical Solutions (CT) to Orchid Orthopedic Solution	
		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'	

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Page 5 of 11

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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Certificate No:

**CE 96026** 

Date:

2020-09-08

Issued To:

NuVasive, Inc. 7475 Lusk Blvd.

San Diego California 92121 USA

Date	Reference Number	Action
19 June 2015	8346477	Certificate Renewal Removal of Significant subcontractors:
		'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.
		Correction of address for significant subcontractors:
		<ul> <li>'Jade Precision Medical Components' from '105A James Way, Southampton, PA 18966, USA' to '3063-B Philmont Avenue, Huntingdon Valley, PA 19006, USA'</li> </ul>
		'DRT Medical LLC' from '818 Greenmount Avenue' to '618 Greenmount Blvd'
		<ul> <li>'Structure Medical LLC' from '2975 South Horseshoe Drive, Naples, Florida, 34104, USA' to '9935 Business Circle, Naples, Florida 34112, USA'</li> </ul>
		<ul> <li>Address clarification of FMI Medisch B.V. to 'De Brauwweg 17, Schiedam 3125 AE, Netherlands"</li> </ul>
		Orchid Anzon Orthopedic solutions, 11911 Clark St., Arcadia, CA 91006, USA
		Change of significant subcontractor trading names:
		From 'Boston Endo Surgical Technologies' to 'Lacey     Manufacturing Co, LLC'

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Page 6 of 11

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Certificate No:

**CE 96026** 

Date:

2020-09-08

Issued To:

NuVasive, Inc. 7475 Lusk Blvd.

San Diego California 92121 **USA** 

Date	Reference Number	Action
		From 'Gamma Service' to 'Synergy Health Radeburg GmbH'
		From 'Tipp Machine & Tool Inc. ' to 'DRT Medical LLC'
		<ul> <li>ANC at 1 Herald Square is now NML, the address and activity remain unchanged.</li> </ul>
		Addition of Significant Subcontractors:
		<ul> <li>'Aeromed, 2342 North Penn road, Hatfield, PA 19440, USA' for the activity Manufacture</li> </ul>
		'Ultra Machining Company (UMC), 500 Chelsea Road, Monticello, MN 55362, USA' for the activity Manufacture
		<ul> <li>'Surface Dynamics LLC, 231 Northland Blvd, Cincinatti, Ohio, 45246, USA' for the activity Manufacture</li> </ul>
		'Quality Tech Services Inc. , 10525 Hampshire Avenue, Bloomington, Minnesota, 55438, USA' Activity: Packaging
		Other changes to the certificate are:
		Remove activity of final inspection for Astro Medical Devices
		<ul> <li>Remove activity of microbiology service for Centurion Sterilization Services</li> </ul>
		Remove activity of final inspection for Culver Tools BV
		Addition of packaging as an activity for DOT GmbH

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Date	Reference Number	Action	
		Remove activity of final inspection for Hoosier	
		Addition of packaging as an activity for Lacey Manufacturing Co, LLC	
		<ul> <li>Remove activity of control of sterilization and add packaging activity for Life Science Outsourcing, Inc.</li> </ul>	
		<ul> <li>Remove activity of final inspection for Orchid Orthopedic Solutions at Raton Dr.</li> </ul>	
		Remove activity of labelling for Remington Medical, Inc.	
21 February 2019	7781017	Traceable to NB 0086.	
21 February 2019 7781017 27 May 2020 3067985		Renewal of Certificate with Scope change:  To add 'image processing software' to the existing scope.  Subcontractor Additions:  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 Carrolton, Ohio, USA facility	

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Date	Reference Number	Action
		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 certifica 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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Date	Reference Number	Action	
		•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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Page 11 of 11

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