



DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000493766-PA-MDSAP-DNK

Initial certification date:
2018-12-18

Expiry Date:
2027-12-17

This is to certify that the management system of

Intuitive Surgical, Inc.

1266 Kifer Road, Sunnyvale, CA, 94086, USA
F005789

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 820

This certificate is valid for the following scope:

The design, manufacture, service and installation of computer-controlled surgical systems and instruments, including endoscopes, surgical instruments, sterile drapes and accessories for use with the computer-controlled systems for surgery.

Design and manufacture of staples and stapling systems.

Design, manufacture, service of Ion Endoluminal System, including Articulating Catheter, Vision Probe, Biopsy Needles, Planning Software and accessories.

Place
Høvik

Effective Date:
2024-12-18



DNV is an MDSAP
Recognized Auditing Organization



For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Tone Kolpus

Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.

Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Address	Site Scope
Intuitive Surgical, Inc. F005789	1. 1266 Kifer Road Building 100, Sunnyvale, CA, 94086, USA	1. Design and development of system and instrument.
	2. 1266 Kifer Road Building 101, Sunnyvale, CA, 94086, USA	2. Quality system, Regulatory affairs, Design and development of systems and instruments. Design, manufacture and service of Ion Endoluminal System, instruments and accessories.
	3. 1266 Kifer Road Building 102, Sunnyvale, CA, 94086, USA	3. Design and development of systems and instruments.
	4. 1266 Kifer Road Building 103, Sunnyvale, CA, 94086, USA	4. Manufacturing of systems; Product Quality, Controlled environment manufacturing; Supplier evaluation and purchasing.
	5. 1450 Kifer Road, Sunnyvale, CA, 94086, USA	5. Manufacturing of accessories, systems and sterile drapes; Receiving, Storage and Shipping of finished goods, Purchasing.
	6. 1020 Kifer Road, Sunnyvale, CA, 94086, USA	6. Business administration.
	7. 3410 Central Expressway, Santa Clara, CA, 95051, USA	7. Installation & Service.
	8. 3875 Kifer Road, Santa Clara, CA, 95051, USA	8. Kitting, Special Labelling, shipping & Distribution of all IS products (systems, I&A); Packaging after product release.
	9. 3420 Central Express Way Santa Clara, CA, California, 95051 USA	9. Research and advanced development activities, design.
	10. 111 Uranium Drive, B117, Sunnyvale, CA, 94086, USA	10. Receiving and warehouse.
Intuitive Surgical, Inc. F005800	1. 1090 Kifer Road, Sunnyvale, CA, 94086, USA	1. Design, Supplier control, Receiving and manufacturing, including controlled environment manufacturing, of instruments and accessories.
	2. 1050 Kifer Road, Sunnyvale, CA, 94086, USA	2. Design, Receiving and manufacturing, including controlled environment manufacturing, of instruments and accessories.

Appendix to Certificate

Intuitive Surgical, S. de R.L. de C.V. F005796	<ol style="list-style-type: none"> 1. Circuito Internacional Sur #21-A, Parque Industrial Nelson - Building B19, Carretera a San Luis R.C. Km 14, 21397, Mexicali, Baja California, Mexico 2. Circuito Internacional Sur #21-A, Parque Industrial Nelson - Building B21, Carretera a San Luis R.C. Km 14, 21397, Mexicali, Baja California, Mexico 	<ol style="list-style-type: none"> 1. Receiving, controlled environment manufacturing of instruments and accessories, storage and shipping of finished products. Manufacture of Ion instruments and accessories. 2. Manufacturing of endoscopic instruments, endoscopes, sub-assembly and controlled environment assembly.
Intuitive Surgical Optics GmbH F005803	Dammweg 1, Baden-Württemberg, 79312 Emmendingen, Germany	Manufacturing, refurbishing, testing, (re)labeling and (re)packaging of Endoscopes and their sub-assemblies. Failure analysis of instruments and accessories.
Intuitive Surgical, Inc. F005797	710 Venture Dr., Suite 300, DeSoto Trade Center Building 1, Southaven, MS, 38672, USA	Manufacturing, Receiving, service, storage, and shipping of finished goods.
Intuitive Surgical, Inc. F005801	4550 W. Watkins St. Suite 120, Phoenix, AZ, 85043, USA	Receiving, Accessories Final Quality Inspection (AFQI), warehousing/storage of finished goods, kitting, replenishment, and shipping of finished goods.
Intuitive Surgical, S. de R.L. de C.V. F005802	Calzada Presidente Venustiano Carranza #1745 Colonia Calles, 21226, Mexicali, Baja California, Mexico	Receiving, sterile and non-sterile manufacturing (including Controlled environment) of surgical instruments, Ion Instruments, catheters, Endoscopes and accessories for surgical and diagnostic systems, including their subassemblies- Sterile and non-sterile. Refurbishment of endoscopes. Storage and shipping of finished goods, purchasing.
Intuitive Surgical, Inc. F006222	3795 Data Drive, Peachtree Corners, GA, 30092, USA	Receiving, IQC, manufacturing/remanufacturing and servicing of systems.