

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: 10000493766-PA-MDSAP-DNK

Initial certification date:  
2018-12-18

Expiry Date:  
2024-12-17

This is to certify that the management system of

## **Intuitive Surgical, Inc.**

1266 Kifer Road, Sunnyvale, California 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

### **United States:**

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

### **Brazil:**

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

### **Japan:**

- MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.155 (2020).
- MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)

### **Canada:**

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

### **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  
2023-11-22

**DNV is an MDSAP authorised  
Auditing Organization**

For the issuing office:  
DNV Product Assurance AS  
Veritasveien 1, 1363 Høvik, Norway



**Tone Elise 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](http://www.dnv.com)

All our Certificates are in blockchain system and as a first step you can validate the certificate details by scanning the QR code on the Certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.

Site Name	Address	Site Scope
Intuitive Surgical, Inc.  F005789	<ol style="list-style-type: none"> <li>1. 1266 Kifer Road Building 100, Sunnyvale, CA, 94086, USA</li> <li>2. 1266 Kifer Road Building 101, Sunnyvale, CA, 94086, USA</li> <li>3. 1266 Kifer Road Building 102, Sunnyvale, CA, 94086, USA</li> <li>4. 1266 Kifer Road Building 103, Sunnyvale, CA, 94086, USA</li> <li>5. 1450 Kifer Road, Sunnyvale, CA, 94086, USA</li> <li>6. 1020 Kifer Road, Sunnyvale, CA, 94086, USA</li> <li>7. 3410 Central Expressway, Santa Clara, CA, 95051, USA</li> <li>8. 3875 Kifer Road, Santa Clara, CA, 95051, USA</li> <li>9. 3420 Central Express Way Santa Clara, CA, California, 95051 USA</li> </ol>	<ol style="list-style-type: none"> <li>1. Design and development of system and instrument.</li> <li>2. Quality system, Regulatory affairs, Design and development of systems and instruments. Design, manufacture and service of Ion Endoluminal System, instruments and accessories.</li> <li>3. Design and development of systems and instruments.</li> <li>4. Manufacturing of systems; Product Quality, Controlled environment manufacturing; Supplier evaluation and purchasing.</li> <li>5. Manufacturing of accessories, systems and sterile drapes; Receiving, Storage and Shipping of finished goods, Purchasing.</li> <li>6. Business administration.</li> <li>7. Installation &amp; Service.</li> <li>8. Kitting, Special Labelling, shipping &amp; Distribution of all IS products (systems, I&amp;A) Packaging after product release.</li> <li>9. Research and advanced development activities, design.</li> </ol>
Intuitive Surgical, Inc.  F005800	<ol style="list-style-type: none"> <li>1. 1090 Kifer Road, Sunnyvale, CA, 94086, USA</li> <li>2. 1050 Kifer Road, Sunnyvale, CA, 94086, USA</li> </ol>	<ol style="list-style-type: none"> <li>1. Design, Supplier control, Receiving and manufacturing, including controlled environment manufacturing, of instruments and accessories.</li> <li>2. Design, Receiving and manufacturing, including controlled environment manufacturing, of instruments and accessories.</li> </ol>
Intuitive Surgical, S. de R.L. de C.V.  F005796	<ol style="list-style-type: none"> <li>1. Circuito Internacional Sur #21-A, Parque Industrial Nelson - Building B19, Carretera a San Luis R.C. Km 14, 21397, Mexicali, Baja California, Mexico</li> <li>2. Circuito Internacional Sur #21-A, Parque Industrial Nelson - Building B21, Carretera a San Luis R.C. Km 14, 21397, Mexicali, Baja California, Mexico</li> </ol>	<ol style="list-style-type: none"> <li>1. Receiving, controlled environment manufacturing of instruments and accessories, storage and shipping of finished products.</li> <li>2. Manufacturing of endoscopic instruments, sub-assembly and controlled environment assembly.</li> </ol>

Intuitive Surgical Optics GmbH F005803	Dammweg 1, Baden-Württemberg, 79312 Emmendingen, Germany	Manufacturing, failure analysis, refurbishing, testing, (re)labeling and (re)packaging of ISI Endoscopes and their subassemblies.
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. F005808	1650 TW Alexander Drive, Durham, NC, 27703, USA	Receiving, manufacturing/remanufacturing of systems and storage 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, Controlled environment manufacturing of Endoscopic instruments, sub-assemblies and Accessories, manufacturing of Endoscopic instruments, sub-assemblies and Accessories, Refurbishing, Testing, Packaging, Relabelling and Repackaging of Endoscopes, Sterile and non-sterile, Storage and shipping of finished goods, purchasing.
Intuitive Surgical, Inc. F006222	<ol style="list-style-type: none"> <li>3795 Data Drive, Peachtree Corners, GA, 30092, USA</li> <li>5400 Triangle Parkway, Peachtree Corners, GA, 30092, USA</li> </ol>	<ol style="list-style-type: none"> <li>Receiving, IQC, manufacturing/remanufacturing of systems and storage of finished goods.</li> <li>Receiving, IQC, and storage of raw materials.</li> </ol>