

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000493768-PA-NA-DNK

Initial certification date:
17 December 2021

Valid:
22 July 2026 – 16 December 2027

This is to certify that the management system of
Intuitive Surgical, Inc.
1266 Kifer Road, Sunnyvale, CA, 94086, USA
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 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, manufacture, service and installation of computer-controlled surgical systems, surgical generators and instruments, including endoscopes, surgical instruments, sterile drapes and accessories for use with the computer-controlled systems.
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 and date:
Høvik, 22 July 2026



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

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Appendix to Certificate

Intuitive Surgical, Inc.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Intuitive Surgical, Inc.	1266 Kifer Road, Sunnyvale, CA, 94086, USA	Building 100: Design and development of system and instrument. Building 101: Quality system, Regulatory affairs, Design and development of systems and instruments, design, manufacture and service of Ion Endoluminal System, instruments and accessories. Building 102: Design and development of systems and instruments. Building 103: Manufacturing of systems; Product Quality, Controlled environment manufacturing; Supplier evaluation and purchasing.
Intuitive Surgical, Inc.	1020 Kifer Road, Sunnyvale, CA, 94086, USA	Business administration.
Intuitive Surgical, Inc.	3420 Central Express Way, Santa Clara, CA, 95051, USA	Research and development, Design.
Intuitive Surgical, Inc.	1090 Kifer Road, Sunnyvale, CA, 94086, USA	Design, Supplier control, Receiving and manufacturing, including controlled environment manufacturing, of instruments and accessories.
Intuitive Surgical, Inc.	1050 Kifer Road, Sunnyvale, CA, 94086, USA	Design, Receiving and manufacturing, including controlled environment manufacturing, of surgical generators, instruments and accessories.
Intuitive Surgical, Inc.	1450 Kifer Road, Sunnyvale, CA, 94086, USA	Manufacturing of accessories, systems and sterile drapes; Receiving, Storage and Shipping of finished goods, Purchasing.
Intuitive Surgical, Inc.	111 Uranium Drive, B117, Sunnyvale, CA, 94086, USA	Receiving and warehouse
Intuitive Surgical, Inc.	3410 Central Express Way, Santa Clara, CA, 95051, USA	Installation & Service
Intuitive Surgical, Inc.	3875 Kifer Road, Santa Clara, CA, 95051, USA	Kitting, Special Labelling, shipping & Distribution of all IS products (systems, I&A) Packaging after product release.
Intuitive Surgical, Inc.	3859 Kifer Road, Santa Clara, CA, 95051, USA	Design and manufacturing of ION systems, Software, instruments and accessories. Receiving.
Intuitive Surgical, Inc.	950 Kifer Road, Sunnyvale, CA, 94086, USA	Receiving, manufacturing, including controlled environment manufacturing, of systems, instruments and accessories.
Intuitive Surgical, Inc.	6503 Cameron Blvd, Gilroy, CA, 95020, USA	Receiving, Incoming Inspection, Kitting and Storage of Raw materials, components and subassemblies, Storage of finished goods.

Site Name	Site Address	Site Scope
Intuitive Surgical, Inc.	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.	Circuito Internacional Sur #21-A, Parque Industrial Nelson - Building B19, Carretera a San Luis R.C. Km 14, 21397, Mexicali, Baja California, Mexico	Building B19: Receiving, controlled environment manufacturing of instruments and accessories, storage and shipping of finished goods. Building B21: Manufacturing of endoscopic instruments, endoscopes, sub-assembly and controlled environment assembly. Manufacture of Ion instruments and accessories.
Intuitive Surgical, S. de R.L. de C.V.	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 Optics GmbH	Dammweg 1, Baden-Württemberg, 79312 Emmendingen, Germany	Manufacturing, refurbishing, testing, (re)labelling and (re)packaging of Endoscopes and their sub-assemblies. Failure analysis of instruments and accessories.
Intuitive Surgical, Inc.	3795 Data Drive, Peachtree Corners, GA, 30092, USA	Receiving, IQC, manufacturing /remanufacturing/refurbishing and servicing of systems. Storage and Shipping of finished goods. Relabelling/repackaging of Instruments & Accessories. Failure analysis of Instruments & Accessories.
Intuitive Surgical, Inc.	5400 Triangle Parkway, Peachtree Corners, GA, 30092, USA	Storage and cleaning of returned carts.
Intuitive Surgical, Sàrl.	1 & 3 Chemin Des Muriers, 1170 Aubonne, Switzerland	Sales, complaint handling, regulatory affairs and customer communication.
Intuitive Surgical, Sàrl.	Rue de l'Ouriette 177, 1170 Aubonne, Switzerland	Sales, complaint handling, regulatory affairs and customer communication.
Intuitive Surgical Bulgaria EOOD	Alexandar Stamboliyski street 27a, 4270, Parvomay, Bulgaria	Manufacturing of endoscopes. Purchasing and receiving.
Intuitive Surgical Optics GmbH	Guerickestraße 1, 79108 Freiburg, Germany	Manufacturing, failure analysis and refurbishing of Endoscopes. Failure analysis of instruments and accessories. Purchasing and receiving.