

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000493768-PA-NA-DNK

Initial certification date:
17 December 2021

Valid:
16 June 2023 – 16 December 2024

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 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, 16 June 2023



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: Receiving and manufacturing of instruments and 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, Supplier control, Receiving and manufacturing, including controlled environment manufacturing, of 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.	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.	710 Venture Dr., Suite 300, DeSoto Trade Center Building 1, Southaven, MS, 38672, USA	Receiving, service, storage and shipping of finished goods.
Intuitive Surgical, Inc.	1650 TW Alexander Drive, Durham, NC, 27703, USA	Receiving, manufacturing/remanufacturing of systems and storage of finished goods.
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.

Site Name	Site Address	Site Scope
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, sub-assembly and controlled environment assembly.
Intuitive Surgical, S. de R.L. de C.V.	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 Optics GmbH	Dammweg 1, Baden-Württemberg, 79312 Emmendingen, Germany	Manufacturing, failure analysis, refurbishing, testing, (re)labeling and (re)packaging of ISI Endoscopes and their sub-assemblies.
Intuitive Surgical, Inc.	3795 Data Drive, Peachtree Corners, GA, 30092, USA	Receiving, IQC, manufacturing/remanufacturing of systems and storage of finished goods.
Intuitive Surgical, Inc.	5400 Triangle Parkway, Peachtree Corners, GA, 30092, USA	Receiving, IQC, and storage of raw materials.
Intuitive Surgical, Sàrl.	1 Chemin des Muriers, 1170 Aubonne, Switzerland	Sales, complaint handling and customer communication.
Intuitive Surgical Optics GmbH	Elzstraße 2, 79350 Sexau, Germany	Failure Analysis for Instruments & Accessories.