

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000493768-PA-NA-DNK

Initial certification date:
17 December 2021

Valid:
17 December 2024 – 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 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, 13 December 2024



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 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. | 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. | 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. Manufacture of Ion instruments and accessories. Building B21: Manufacturing of endoscopic instruments, endoscopes, 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, 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 and servicing of systems. |
| 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 Optics GmbH | Elzstraße 2, 79350 Sexau, Germany | Failure Analysis for Instruments & Accessories. |