



# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:

10000464204-PA-NoMA-DNK Rev 0.0

Project No.:

PRJN-246256-2021-PA-DNK

Valid Until

06 February 2024

This is to certify that the quality system of:

**Intuitive Surgical, Inc.**

1266 Kifer Road, Sunnyvale, CA 94086, USA

For design, production and final product inspection/testing of:

**Computer-controlled surgical systems and instruments, including endoscopes, surgical instruments and sterile/non-sterile accessories for use with the computer-controlled systems, staples and stapler reloads**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:

Høvik, 21 May 2021

For the issuing office:

**Notified Body 2460**  
**DNV Product Assurance AS**



*Eugenie Winger Husebye*  
**Eugenie Winger Husebye**  
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-11-MDD-f2, rev.0

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

## Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM-343 to DNV Product Assurance AS (NB 2460)	21 May 2021

## Products covered by this Certificate:

Product Description	Product Name	Class
Scissors	Potts Scissors, Round Tip Scissors, Curved Scissors	IIa
Clip Applier	Small Clip Applier, Large Clip Applier, Medium-Large Clip Applier, Medium-Large Clip Applier	
Needle Driver	Large Needle Driver, Needle Driver, Mega Needle Driver, Large SutureCut Needle Driver, Mega Suture Cut Needle Driver, Curved Needle Driver, Wristed Needle Driver	
Forceps (dissector)	Black Diamond Micro Forceps, Debakey Forceps, Long Tip Forceps, Cadiere Forceps, Maryland Dissector, Resano Forceps, Tenaculum Forceps	
Grasper	ProGrasp Forceps, Schertel Grasper, Bowel Grasper, Double Fenestrated Grasper, Cobra Grasper, Cardiac Probe Grasper, Thoracic Grasper, Black Diamond Micro Forceps, Tenaculum Forceps, Tip-Up Fenestrated Grasper, Resano Forceps, Small Grasping Retractor, Long Tip Forceps, Cadiere Forceps, DeBakey Forceps, Fundus Grasper, Crocodile Grasper	
Tissue Manipulators	Atrial Retractor, Short Right; Dual Blade Retractor, Grasping Retractor, Small Grasping Retractor, Valve Hook	
Instrument Introduction Device	8mm Instrument Cannula; 8mm Instrument Cannula, Long; 8mm Cannula with Outlet; Cannula, 8.5mm Endoscope Cannula; 8mm Cannula with Outlet, Long; 5mm Instrument Cannula; 8mm to 5mm Cannula Reducer; 12mm Instrument Cannula; Single-Site 5 x 300 mm Flexible Blunt Obturator; Single-Site 10 mm	

	Accessory Cannula; Single-Site 10 mm Blunt Obturator; 5mm Flared Cannula; Single-Site 5 x 250 mm Flexible Blunt Obturator; Endowrist Stapler Cannula; Endowrist Stapler Cannula Reducer; 12-8 Reducer; 12 mm & Stapler Cannula; 12 mm & Stapler Cannula, Long; 8 mm Hasson Cone; 12 mm & Stapler Hasson Cone; 8 mm Bladeless Optical Obturator; 8 mm Bladeless Optical Obturator, Long; 8 mm Flared/Grounded Cannula; Single-Site 8 mm Obturator; Single-Site 5 x 300 mm Curved Cannula (Endoscope Right); Single-Site 5 x 300 mm Curved Cannula (Endoscope Left); Single-Site Port for 8 mm Endoscope; Single-Site 5 x 250 mm Curved Cannula (Endoscope Right); Single-Site 5 x 250 mm Curved Cannula (Endoscope Left); Single-Site 5 mm Accessory Cannula; 5 – 10 mm Single-Site Cannula Seal; Single-Site Cannula, 8 mm Camera; Single-Site 5 mm Accessory Obturator	
Suction/Irrigation Instrument	EndoWrist One Suction Irrigator, Suction Irrigator	
Instrument Control Boxes	Instrument Control Box, Model ICB3000, Instrument Control Box Kit Upgrade Kit	
Instrument Covers and sheaths	Tip Cover Accessory, EndoWrist® Stapler Sheath	
Snap-Fit Instrument	Snap-fit Blue Blade, Snap-fit Paddle Blade, Snap-Fit Scalpel Instrument	
Stereo Endoscope and Camera	8 mm Endoscope, 0°; 8 mm Endoscope, 30°; 8mm Endoscope Plus, 0 degree; 8mm Endoscope Plus, 30 degrees	
Stapler	EndoWrist® Stapler 45, EndoWrist® Stapler 30, EndoWrist® Stapler 30 Curved-Tip, EndoWrist® Stapler 45 Curved-Tip, SureForm® 60, SureForm® 45 Straight Tip, SureForm® 45 Curved Tip	
Bipolar Forceps	Precise Bipolar Forceps, Micro Bipolar Forceps, Maryland Bipolar Forceps, Fenestrated Bipolar Forceps, PK Dissecting Forceps, Curved Bipolar Dissector, Endowrist One Vessel Sealer, Long Bipolar Grasper, Bipolar Maryland, EndoWrist Vessel Sealer Extend, Force Bipolar, SynchroSeal	IIb
Monopolar ESU Instrument	Monopolar Cautery; Monopolar Curved Scissors; Permanent Cautery Hook; Permanent Cautery Spatula; Cautery Spatula Tip, 5mm; Cautery Hook Tip 5 mm	
Model IS 3000	Model IS3000 da Vinci Si Surgical System - Patient	

	Side Cart, Model IS3000 da Vinci Si Surgical System - Surgeon Console, Model IS3000 da Vinci Si Surgical System - Vision System, Model IS3000 da Vinci Si Surgical System – Core, Model IS3000 da Vinci Si Surgical System - DoCo	
Harmonic Curved Shears & Insert	Harmonic ACE Curved Shears, Harmonic ACE Curved Shears Insert Harmonic ACE® Curved Shears	
Model IS 4000	Model IS4000 da Vinci Xi Surgical System - Patient Cart, Model IS4000 da Vinci Xi Surgical System - Surgeon Console, Model IS4000 da Vinci Xi Surgical System - Vision Cart	
Stapler reloads w. staples	EndoWrist® Stapler 45 Reload, Green; EndoWrist® Stapler 45 Reload, Blue; EndoWrist® Stapler 45 Reload, White; EndoWrist® Stapler 30 Reload, Green; EndoWrist® Stapler 30 Reload, Blue; EndoWrist® Stapler 30 Reload, White; EndoWrist® Stapler 30 Reload, Gray; SureForm® 60 Reload, Green; SureForm® 60 Reload, Blue; SureForm® 60 Reload, White; SureForm® 60 Reload, Black; SureForm® 45 Reload, White; SureForm® 45 Reload, Blue; SureForm® 45 Reload, Green; SureForm® 45 Reload, Black; SureForm® 45 Reload, Gray	
Model IS 4200	Model IS4200 da Vinci X Surgical System - Patient Cart	
Electrosurgical Generators	E-100 Generator	
Drape	Instrument Arm Drape, Column Drape, Arm 4 Extension Drape	
Cannula Seal	5-8 mm Cannula Seal, 12 mm & Stapler Cannula Seal, Universal Cannula Seal (5-12 mm), 8mm Cannula Seal	Is

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

Site Name	Address
Intuitive Surgical, Inc.	1266 Kifer Road, Sunnyvale, CA 94086, USA
Intuitive Surgical Inc.	1090 Kifer Road, Sunnyvale, CA 94086, USA
Intuitive Surgical Inc.	1050 Kifer Road, Sunnyvale, CA 94086, USA
Intuitive Surgical Inc.	1450 Kifer Road, Sunnyvale, CA 94086, USA
Intuitive Surgical Inc.	3410 Central Expressway, Santa Clara, CA 95051, USA
Intuitive Surgical Inc.	3875 Kifer Road, Sunnyvale, CA 94086, USA
Intuitive Surgical Inc.	1650 TW Alexander Drive, Durham, NC 27703, USA
Intuitive Surgical Inc.	710 Venture Dr., Suite 300, DeSoto Trade Center Building 1, Southaven, MS 38672, USA
Intuitive Surgical Service Optics, Inc.	722 Plantation Street, Worcester, MA 01605, USA
Intuitive Surgical Inc.	4550 W. Watkins St., Suite 120, Phoenix, AZ 85043, USA
Intuitive Surgical S. de R.L. de C.V.	Circuito Internacional Sur #21-A, Parque Industrial Nelson, Carretera a San Luis R.C. Km 14, Mexicali B.C.C.P. 21397, Mexico
Intuitive Surgical S. de R.L. de C.V.	Circuito Internacional Norte #8, Parque Industrial Nelson Carretera a San Luis R.C., Km 14, Mexicali B.C.C.P. 21397, Mexico
Intuitive Surgical, Sàrl	1 Chemin des Mûriers, 1170 Aubonne, Switzerland
Intuitive Surgical S. de R.L. de C.V.	Calzada Presidente Venustiano Carranza #1745 Colonia Calles, Mexicali B.C.C.P. 21226, Mexico
Intuitive Surgical Optics GmbH	An der Amtmannsmühle 11, 35444 Biebertal, Germany
Intuitive Surgical Optics GmbH	Dammweg 1, 79312 Emmendingen, Germany

### EU Representative

Intuitive Surgical, Sàrl, 1 Chemin des Mûriers, 1170 Aubonne, Switzerland

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate