EC DECLARATION OF CONFORMITY

IS4000 Class I Accessories

PRODUCT IDENTIFICATION	
Model/Part Number	Product Name
400498	Endoscope Sterilization Tray
400482	Automated Washer Connector Set
400490	8 mm Endoscope Sterilization Tray
381216	*EndoWrist®* Instrument Release Kit
381xxx*	*EndoWrist®* Instrument Release Kit, Language
381307	*EndoWrist®* Instrument Release Kit, Czech
381308	*EndoWrist®* Instrument Release Kit, Danish
381309	*EndoWrist®* Instrument Release Kit, Dutch
381311	*EndoWrist®* Instrument Release Kit, French
381312	*EndoWrist®* Instrument Release Kit, German
381315	*EndoWrist®* Instrument Release Kit, Italian
381327	*EndoWrist®* Instrument Release Kit, Spanish
381328	*EndoWrist®* Instrument Release Kit, Swedish
381329	*EndoWrist®* Instrument Release Kit, Turkish
342562	8 mm Instrument Introducer
470397	8 mm Cannula Gage Pin
470383	Monopolar Cautery Cord
470384	Bipolar Cautery Cord
371716	Energy Activation Cable, Covidien Force Triad
470629	Universal Reprocessing Hardware Kit***
381215	EndoWrist Stapler Release Kit, English
381xxx**	EndoWrist Stapler Release Kit, Language

* The EndoWrist Instrument Release Kit has instructions attached to it that gets translated per national language requirements of all countries where it is sold. A unique number is assigned for each translated language with the starting three numbers (381) remaining constant. The complete Product Identification includes the Part Number and Product Name that is unique for each language version.

** The EndoWrist Stapler Release Kit has instructions attached to it that gets translated per national language requirements of all countries where it is sold. A unique number is assigned for each translated language with the starting three numbers (381) remaining constant. The complete Product Identification includes the Part Number and Product Name that is unique for each language version.

*** The Universal Reprocessing Hardware Kit P/N 470629 is also compatible with the da Vinci, da Vinci S and da Vinci Si Instruments and Accessories.

MANUFACTURER		
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AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Telephone
Intuitive Surgical, SAS	11 avenue de Canteranne 33600 Pessac, France	+33 1 77 68 88 45

REGISTRATION AND TECHNICAL INFORMATION			
Notified Body Name	Notified Body ID#	EC Certificate Number	Technical File Number
N/A	N/A	N/A	851173

CONFORMITY ASSESSMENT FOR MDD	
Route to Compliance: Annex VII of MDD 93/42/EC Council Directive	
Product Model/Part Number	Device Classification
All products	Class I Rule 1 Per Annex IX of MDD 93/42/EEC

Intuitive Surgical, Inc., hereby declares that the above mentioned products conform to the applicable provisions of the following directive:

Medical Devices Directive 93/42/EEC as amended by 2007/47/EC

This declaration of conformity is issued under the sole responsibility of the manufacturer. This declaration is valid for all products described above and bearing the CE marking originating from Intuitive Surgical. This Declaration of Conformity becomes effective on the signature date (below) for the products indicated above. All supporting documentation is retained by the manufacturer.

COMPANY REPRESENTATIVE: Mario Lowe

SIGNATURE: Mario Lowe DATE: June 28, 2021

TITLE: Sr. Director, Regulatory Affairs

LOCATION: Sunnyvale, California, USA