

## EC DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION	
Model/Part Number/Version <sup>1</sup>	Product Name
470015	Instrument Arm Drape
470341	Column Drape
470473	ARM 4 Extension Drape
470361	5-8 mm Cannula Seal
470380	12 mm & Stapler Cannula Seal
470381	12-8 mm Reducer
470359	8 mm Bladeless Obturator
470360	8 mm Bladeless Obturator, Long

MANUFACTURER		
Name of Company	Address	Telephone
Intuitive Surgical, Inc.	1266 Kifer Road Sunnyvale, CA 94086 USA	+1 (408) 523-2100

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
DNV Product Assurance AS	2460	10000464204-PA- NoMA-DNK Rev 0.0	851171

CONFORMITY ASSESSMENT FOR MDD	
Route to Compliance: Annex II of MDD 93/42/EEC Council Directive	
Product Model/Part Number/Version	Device Classification
470015	Class Is (sterile) Rule I Per annex IX of MDD 93/42/EEC
470341	
470473	
470361	
470380	
470381	Class IIa Rule 7 Per Annex IX of MDD 93/42/EEC
470359	
470360	

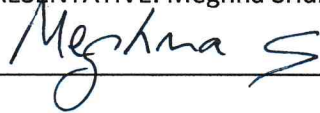
Intuitive Surgical, Inc., hereby declares that the above mentioned products conform to the applicable provisions of the following directive:

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: Meghna Sridharan

SIGNATURE: \_\_\_\_\_



DATE: 06 December, 2021

TITLE: Senior Director Regulatory Affairs Operations & Indirect Markets

LOCATION: Sunnyvale, California, USA