



## EC DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION	
Model/Part Number/Version <sup>1</sup>	Product Name
470002	8 mm Instrument Cannula
470004	8 mm Instrument Cannula, Long
470008	8 mm Blunt Obturator
470009	8 mm Blunt Obturator, Long
470398	8 mm Hasson Cone
470375	12 mm & Stapler Cannula
470389	12 mm & Stapler Cannula, Long
470376	12 mm & Stapler Blunt Obturator
470390	12 mm & Stapler Blunt Obturator, Long
470395	12 mm & Stapler Bladeless Obturator
470396	12 mm & Stapler Bladeless Obturator, Long
470399	12 mm & Stapler Hasson Cone
470319	8mm Flared/Grounded Cannula

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 (Annex II)			
Notified Body Name	Notified Body ID#	EC Certificate Number	Technical File Number
DNV Product Assurance AS	2460	10000464204-PA-NoMA-DNK Rev 0.0	851172
REGISTRATION AND TECHNICAL INFORMATION (Annex VII)			
Notified Body Name	Notified Body ID#	EC Certificate Number	Technical File Number
N/A	N/A	N/A	851172

**CONFORMITY ASSESSMENT FOR MDD**

Route to Compliance: Annex II of MDD 93/42/EEC Council Directive

Product Model/Part Number

Device Classification

470002

Class IIa

470004

Rule 7

470375

Per Annex IX of MDD 93/42/EEC

470389

470398

470399

470319

Route to Compliance: Annex VII of MDD 93/42/EEC Council Directive

Product Model/Part Number

Device Classification

470008

Class I

470009

Rule 6

470376

Per Annex IX of MDD 93/42/EEC

470390

470395

470396

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:



DATE:

26 May 2021

TITLE: Senior Director Regulatory Affairs

LOCATION: Sunnyvale, California, USA