



EC DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION	
Model/Part Number/Version ¹	Product Name
470298	<i>EndoWrist</i> [®] Stapler 45
470545	<i>EndoWrist</i> [®] Stapler 45 Curved-Tip
48445G	<i>EndoWrist</i> [®] Stapler 45 Reload, Green
48645B	<i>EndoWrist</i> [®] Stapler 45 Reload, Blue
48645W	<i>EndoWrist</i> [®] Stapler 45 Reload, White
410370	<i>EndoWrist</i> [®] Stapler Sheath
470430	<i>EndoWrist</i> [®] Stapler 30
470530	<i>EndoWrist</i> [®] Stapler 30 Curved-Tip
48630G	<i>EndoWrist</i> [®] Stapler 30 Reload, Green
48630B	<i>EndoWrist</i> [®] Stapler 30 Reload, Blue
48630W	<i>EndoWrist</i> [®] Stapler 30 Reload, White
48630M	<i>EndoWrist</i> [®] Stapler 30 Reload, Gray
480460	<i>SureForm</i> [®] 60
48360G	<i>SureForm</i> [®] 60 Reload, Green
48360B	<i>SureForm</i> [®] 60 Reload, Blue
48360W	<i>SureForm</i> [®] 60 Reload, White
48360T	<i>SureForm</i> [®] 60 Reload, Black
480445	<i>SureForm</i> 45 Straight Tip
480545	<i>SureForm</i> 45 Curved Tip
48345W	<i>SureForm</i> [®] 45 Reload, White
48345B	<i>SureForm</i> [®] 45 Reload, Blue
48345G	<i>SureForm</i> [®] 45 Reload, Green
48345T	<i>SureForm</i> [®] 45 Reload, Black
48345M	<i>SureForm</i> [®] 45 Reload, Gray

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	1009642

CONFORMITY ASSESSMENT FOR MDD	
Route to Compliance: Annex II of MDD 93/42/EC Council Directive	
Product Model/Part Number/Version	Device Classification
470298 (Stapler 45)	Class IIa Rule 6 Per annex IX of MDD 93/42/EC
470545 (Stapler 45 Curved-Tip)	
410370 (Sheath)	
470430 (Stapler 30)	
470530 (Stapler 30 Curved-Tip)	
480460 (Stapler 60 instrument)	
480445 (SureForm 45, Straight Tip)	
480545 (SureForm 45, Curved Tip)	
48445G (Stapler 45 Green Reload)	Class IIb Rule 8 Per annex IX of MDD 93/42/EC
48645B (Stapler 45 Blue Reload)	
48645W (Stapler 45 White Reload)	
48630G (Stapler 30 Green Reload)	
48630B (Stapler 30 Blue Reload)	
48630W (Stapler 30 White Reload)	
48630M (Stapler 30 Gray Reload)	
48360G (SureForm 60 Green Reload)	
48360B (SureForm 60 Blue Reload)	
48360W (SureForm 60 White Reload)	
48360T (SureForm 60 Black Reload)	
48345W (SureForm 45, White Reload)	
48345B (SureForm 45, Blue Reload)	
48345G (SureForm 45, Green Reload)	
48345T (SureForm 45, Black Reload)	
48345M (SureForm 45, Gray Reload)	

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: 26 May 2021

TITLE: Senior Director Regulatory Affairs

LOCATION: Sunnyvale, California, USA