

EU Declaration of Conformity

1. Manufacturer and European Representative Information:

Manufacturer Name	Reach Surgical, Inc.
Manufacturer Address	120 Xinxing Road, West Zone, TEDA 300462 Tianjin P.R. China
Manufacturer SRN Code	CN-MF-000011148
European Representative (MDR)	MDSS GmbH
European Representative Address	Schiffgraben 41, 30175 Hannover, Germany
European Representative SRN Code	DE-AR-000005430

2. Product Information

Product Name/ Description	Trade Name	Models	Basic UDI-DI
Single Use Loading Units for Endoscopic Linear Cutting Staplers	ENDO REACH RLC Reload Units	ENDO RLC4525L, ENDO RLC4535L, ENDO RLC4548L, ENDO RLC6025L, ENDO RLC6035L, ENDO RLC6040L, ENDO RLC6048L,	69538158H3632
	ENDO REACH SRC Reload Units	ENDO SRC4525L, ENDO SRC4535L, ENDO SRC4548L, ENDO SRC6025L, ENDO SRC6035L, ENDO SRC6048L, ENDO SRC6040L, ENDO SRC4525BL, ENDO SRC4535BL, ENDO SRC4548BL, ENDO SRC6025BL, ENDO SRC6035BL, ENDO SRC6040BL, ENDO SRC6048BL,	
	ENDO REACH RLC Reload Units	ENDO RLC4525R, ENDO RLC4535R, ENDO RLC4548R, ENDO RLC6025R, ENDO RLC6035R, ENDO RLC6040R, ENDO RLC6048R	69538158H3836
	ENDO REACH SRC Reload Units	ENDO SRC4525R, ENDO SRC4535R, ENDO SRC4548R, ENDO SRC4550R ENDO SRC6025R, ENDO SRC6035R, ENDO SRC6048R, ENDO SRC6040R, ENDO SRC6050R	
	ENDO REACH SRC Reload Units	ENDO SRC4525BR, ENDO SRC4535BR, ENDO SRC4548BR, ENDO SRC4550BR, ENDO SRC6025BR, ENDO SRC6035BR, ENDO SRC6040BR, ENDO SRC6048BR, ENDO SRC6050BR	
	ENDO REACH AFT Reload Units	ENDO AFT45TNR, ENDO AFT45PLR, ENDO AFT45BKR, ENDO AFT60TNR, ENDO AFT60PLR, ENDO AFT60BKR ENDO AFT45TNBR, ENDO AFT60TNBR, ENDO AFT45PLBR, ENDO AFT60PLBR	69538158H442QW
	ENDO REACH REC Reloads	REC45GRA, REC45WHT, REC45BLU, REC45GLD, REC60GRA, REC60WHT, REC60BLU, REC60GLD,	69538158P634D

Reload Units	IREACH OMNIA Reload Units	ID3020, ID4520, ID6020, ID3025, ID4525, ID6025, ID4535, ID6035, ID4548, ID6048,	69538158W427UB
		ID3020B, ID4520B, ID6020B, ID3025B, ID4525B, ID6025B, ID4535B, ID6035B,	
		ID30TAN, ID45TAN, ID60TAN, ID30PUL, ID45PUL, ID60PUL, ID45BLK, ID60BLK,	69538158W642UH
		ID30TANB, ID45TANB, ID60TANB, ID30PULB, ID45PULB, ID60PULB	
Intended Use		This instrument is intended for transection, resection of tissues and/or creation of anastomoses.	
EMDN Code		H020301 LINEAR STAPLERS, VIDEO-ASSISTED SURGERY	
Classification		Class IIb, Rule 8 first sentence	

We Reach Surgical, Inc. herewith declare under our sole responsibility that the above mentioned products meet the transposition into national law which apply to it. The provisions of following EC Council Regulation and Union legislation.

Medical Device Regulation:

Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices (MDR 2017/745).

Notified Body:

TÜV Rheinland LGA Products GmbH
 Tillystraße 2, 90431, Nürnberg, Germany

NB Identification Number:

CE 0197

Conformity assessment procedure:

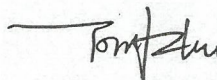
Annex IX (Chapter I, Section 2 and 3 and Chapter III)

EU Certification:

HZ 2064405-1

Reach Surgical, Inc

Represented by Management Representative: Tony Zhu



Tianjin, China 30th Nov, 2023

Place, date

 Name and Function

Revision History

Version	Revision reason	Revision Description	Revised by	Date
X.0	/	First issue for MDR.	Echo	2023-10-14
X.1	Modify according to verification process of MDSS GmbH.	<ol style="list-style-type: none">1. Add Reach's company logo/MDSS SRN code/Reference CS/Additional Information/Directive2011/65/EU/2015/86 3/EC/Revision History;2. Update the name of MDSS GmbH;3. Update Conformity assessment procedure and EC Certification.	Echo	2023-11-30

