

## EC Declaration of Conformity

### 1. Manufacturer and European Representative Information:

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

### 2. Product Information

<b>Product Name/Description</b>	Powered Articulating Staplers	Endoscopic Motorized Cutting Staplers	
<b>Trade Name</b>	IREACH OMNIA Staplers	IREACH MAGNUM Staplers	/
<b>Models</b>	IDL, IDM, IDS	IM 60AL, IM45AL, IM60AS, IM45AS, IM60AM, IM45AM	ENDO SRC TS, ENDO SRC T, ENDO SRC TL, ENDO SRC TSZ, ENDO SRC TZ, ENDO SRC TLZ, ENDO SRC PS, ENDO SRC P, ENDO SRC PL, ENDO SRC PSZ, ENDO SRC PZ, ENDO SRC PLZ
<b>Basic UDI-DI</b>	69538158W014S	69538158U004E	69538158J002P
<b>Intended Use</b>	This instrument is intended for transection, resection of tissues and/or creation of anastomoses.		
<b>EMDN Code</b>	H020301 LINEAR STAPLERS, VIDEO-ASSISTED SURGERY		
<b>Classification</b>	Class IIa, Rule 9 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).

#### Directive:

2011/65/EU :The restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).

2015/863/EC: Amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

**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)

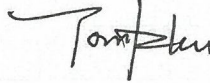
**EU Certification:** HZ 2064405-1

Tianjin, China 30th Nov, 2023

Place, date

Reach Surgical, Inc

Represented by Management Representative: Tony Zhu



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Name and Function

**Revision History**

<b>Version</b>	<b>Revision reason</b>	<b>Revision Description</b>	<b>Revised by</b>	<b>Date</b>
X.0	/	First issue for MDR.	Echo	2022-07-20
X.1	Modify according to verification report of MDSS GmbH.	<ol style="list-style-type: none"><li>1. Add Reach's company logo/MDSS SRN code/Reference CS/Additional Information/Directive2011/65/EU/2015/86 3/EC/Revision History;</li><li>2. Update the name of MDSS GmbH;</li><li>3. Update Conformity assessment procedure and EC Certification.</li></ol>	Echo	2023-11-30

