Summary of safety and clinical performance

（SSCP）

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the instructions for use as the main document to ensure the safe use of Single Use Loading Units for Endoscopic Linear Cutting Staplers and Reload Units, nor to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

Contents

1. Device identification and general information

1.1 Device trade names

ENDO REACH RLC Reload Units

ENDO REACH SRC Reload Units

ENDO REACH AFT Reload Units

ENDO REACH REC Reloads

IREACH OMNIA Reload Units

1.2 Manufacturer's name and address

Name: Reach Surgical. Inc

Address: 120 Xinxing Road, West Zone, TEDA, 300462 Tianjin, P.R.China

1.3 Manufacturer's SRN

SRN Code: CN-MF-000011148

1.4 Basic UDI-DI

Tabel-1 Product and models and basic UDI-DI information

Product Name	Models	Basic UDI-DI	Difference
Single Use Loading Units for Endoscopic Linear Cutting Staplers	ENDO RLC4525L	69538158H3632	L: Refer to straight function when connect with Endo Endoscopic Linear Cutting Staplers, all of the models are mirror different in tip top structure and size, The intended use and classification is same
	ENDO RLC4535L		
	ENDO RLC4548L		
	ENDO RLC6025L		
	ENDO RLC6035L		
	ENDO RLC6040L		
	ENDO RLC6048L		
	ENDO SRC4525L		
	ENDO SRC4535L		
	ENDO SRC4548L		
	ENDO SRC6035L		
	ENDO SRC6040L		
	ENDO SRC6025L		
	ENDO SRC4550L		
	ENDO SRC6048L		
	ENDO SRC6050L		
	ENDO SRC4525BL		

	ENDO SRC4535BL		
	ENDO SRC4548BL		
	ENDO SRC4550BL		
	ENDO SRC6025BL		
	ENDO SRC6035BL		
	ENDO SRC6040BL		
	ENDO SRC6048BL		
	ENDO SRC6050BL		
	ENDO RLC4525R		R: Bent function when connect with Endoscopic Linear Cutting Staplers all of the models are mirror different in tip top structure and size, The intended use and classification is same
	ENDO RLC4535R		
	ENDO RLC4548R		
	ENDO RLC6025R		
	ENDO RLC6035R		
	ENDO RLC6040R		
	ENDO RLC6048R		
	ENDO SRC4525R		
	ENDO SRC4535R		
	ENDO SRC4548R		
	ENDO SRC6025R		
	ENDO SRC6035R		
	ENDO SRC6040R	69538158H3836	
	ENDO SRC6048R		
	ENDO SRC4550R		
	ENDO SRC6050R		
	ENDO SRC4525BR		
	ENDO SRC4535BR		
	ENDO SRC4548BR		
	ENDO SRC4550BR		
	ENDO SRC6025BR		
	ENDO SRC6035BR		
	ENDO SRC6040BR		
	ENDO SRC6048BR		
	ENDO SRC6050BR		
	ENDO AFT45TNR		There are different high size of Ti staple compare with Endo RLC\SRC xxxL and R.
	ENDO AFT45PLR		
	ENDO AFT45BKR		
	ENDO AFT60TNR	69538158H442QW	
	ENDO AFT60PLR		
	ENDO AFT60BKR		
	ENDO AFT45TNBR		

	ENDO AFT45PLBR		
	ENDO AFT60TNBR		
	ENDO AFT60PLBR		
	REC45GRA	69538158P634D	The design structure and size are different with Endo RLC\SRC\AFT
	REC45WHT		
	REC45BLU		
	REC45GLD		
	REC45GRN		
	REC45BLK		
	REC60GRA		
	REC60WHT		
	REC60BLU		
	REC60GLD		
	REC60GRN		
	REC60BLK		

Product Name	Models	Basic UDI-DI	Different
Reload Units	ID3020	69538158W427UB	Design structure is same with AFT series, just size and parts of connect with Handel are different.
	ID4520		
	ID6020		
	ID3025		
	ID4525		
	ID4535		
	ID4548		
	ID6025		
	ID6035		
	ID6048		
	ID3020B		
	ID4520B		
	ID6020B		
	ID3025B		
	ID4535B		
	ID6035B		
	ID4525B		
	ID6025B		
	ID30TAN	69538158W642UH	There are different high size of Ti staple compare with Powered Endo ID series.
	ID30PUL		
	ID45TAN		
	ID45PUL		
	ID45BLK		

	ID60TAN		
	ID60PUL		
	ID60BLK		
	ID30TANB		
	ID45TANB		
	ID30PULB		
	ID45PULB		
	ID60TANB		
	ID60PULB		

1.5 Medical device nomenclature description

EMDN code: H020301 LINEAR STAPLERS, VIDEO-ASSISTED SURGERY

1.6 Class of device

Class II b

1.7 Year when the first certificate (CE) was issued covering the device

Endo RLC xxx: 2011

Endo SRC xxx: 2017

Endo REC xxx: 2018

Endo AFT xxx: 2020

1.8 Authorised representative name and the SRN

AR Name: Medical Device Safety Service GmbH

SRN: DE-AR-000005430

1.9 NB's name and the NB's single identification number

NB Name: TÜV Rheinland LGA Products GmbH

Single Identification Number: 0197

2. Intended use of the device

2.1 Intended purpose

This instrument is intended for transection, resection of tissues and/or creation of anastomoses.

2.2 Indication(s) and target population(s)

Indications:

Single Use Loading Units for Endoscopic Linear Cutting Staplers (Endo RLC xxx and Endo SRC xxx and Endo AFT xxx) are intended for transection, resection and/or creation of anastomoses. It has applications in open and minimally invasive surgeries including thoracic, abdominal, gynecological, urological surgeries. It may be used for transection and resection of lungs, bronchial tissue, intestines, stomach, kidney, uterus etc.

Reload Units（ID xxx）is intended to be used with the Powered Articulating Staplers for transection, resection and/or creation of anastomoses. It has applications in open and minimally invasive surgeries including thoracic, abdominal, gynecological, urological surgeries. It may be used for transection and resection of lungs, bronchial tissue, intestines, stomach, urethra, kidney, uterus etc.

Target population(s)

Endo RLC xxx and Endo SRC xxx and Endo AFT xxx

General population requiring resection and reconstruction of organs and tissues in the thoracic and abdominal cavities.

ID xxx

General population, including adults and children.

2.3 Contraindications or restrictions for use or limitations

Contraindications

Endo RLC xxx and Endo SRC xxx and Endo AFT xxx

- Tissue edema, the muscular layer is too thick, the coalesce ability is bad;
- Those that are suspected that there are cancer tissues left at the incisal side, or the incisal side is damaged seriously.

REC xxx

- Do not use The instruments on the aorta.
- Do not use The instruments on ischemic or necrotic tissue.

- Do not use on major vessels without making provision for proximal and distal control.
- Tissue thickness should be carefully evaluated before applying any stapler. Refer to Reload Staple Size Chart below for a guide to staple size selection. If tissue cannot be comfortably compressed to the closed staple height or easily compresses to less than the closed staple height, the tissue is contraindicated as it may be too thick or too thin for the selected staple size.
- The instruments are not intended for use when surgical stapling is contraindicated.

ID xxx

- Do not use the Instrument on the aorta.
- Do not use the Instrument on ischemic or necrotic tissue.
- Do not use the Instrument on major vessels without making provision for proximal and distal control.
- Tissue thickness should be carefully evaluated before firing. Refer to the Chart 01 – Reload Units Product Codes for tissue compression requirement (Closed Staple Height) for each staple size. If tissue cannot comfortably compress to the closed staple height, or easily compresses to less than the closed staple height, the tissue is contraindicated as it may be too thick or too thin for the selected staple size.
- The Instrument is not intended for use when surgical stapling is contraindicated.

Restrictions

Endo RLC xxx and Endo SRC xxx and Endo AFT xxx

- Only use the Staplers with the ENDO REACH Reloads manufactured by Reach Surgical, Inc. Staplers **may be reloaded and fired no more than 25 times in a single procedure.**
- When The Stapler is used with a 4.8 mm and 5.0mm Reload, a black (4.0mm,4.5mm,5.0mm) Reload, the instrument MUST be introduced through a 15.5 mm trocar. A smaller size trocar will not be suitable for the 4.8,5.0 Reload and a black Reload.

REC xxx

- Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or staple line disruption.

- Do not load the instrument more than 12 times for a maximum of 12 firings per instrument.

ID xxx

- Examine the shipping carton and instrument for signs of shipping damage. Note any shortages, breakage, or apparent damage, retain the evidence, notify Customer Service or Distributor immediately and replace with a new instrument. Do not use a damaged product.
- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Instruments for minimally invasive procedure may vary in diameter from manufacturer to manufacturer. When such instruments and accessories from different manufacturers are employed together in a procedure, verify their compatibility prior to procedure.
- Do not use the instrument if the shaft is visibly bent.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- The instrument must be disposed after procedure once the package is opened.
- The instrument is designed, inspected, and manufactured for single procedure only. Do not reuse, reprocess or resterilize the instrument as it may compromise the structural integrity of the instrument, and/or lead to instrument failure that in turn may result in patient injury, illness, or death.
- Reusing the instrument may create risk of contamination, infection or cross-infection, including, but not limited to, the transmission of infectious diseases, which may lead to injury, illness, or death.
- Do not load the instrument more than 16 times. The instrument can fire for a maximum number of 16 times. Use of staple line reinforcement material may reduce the maximum number of firings.

- After removing the Shipping Wedge, observe the surface of the new Reload. The Reload Units must be replaced with another Reload Units if any staple tray is visible. (If staple tray is visible, the Reload may not contain staples.)
- Do not articulate when the jaws are closed.
- When selecting the Reload, careful consideration should be given to existing pathologic conditions as well as any pre-surgical treatment, such as radiotherapy, that the patient may have undergone. Certain conditions or preoperative treatments may cause change in tissue thickness that would exceed the indicated range of tissue thickness for the standard choice of Reload.
- Do not use hospital autoclaves to sterilize or disinfect Battery and the instrument.
- Use of any other type of battery other than the battery supplied with the instrument may result in increased EMISSIONS or decreased IMMUNITY of the instrument.
- Avoid using the instrument adjacent to or stacked with another equipment. If it is necessary to use the instrument adjacent or stacked with another instrument, pay attention and notice any abnormalities.
- Do not modify the instrument without authorization from the manufacturer.
- Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this instrument and result in improper function.
- If the hemostasis of the staple line cannot be clearly observed, do not continue using this instrument.
- The instrument must be used in a specified electromagnetic environment. For more information, refer to **Guidance and manufacturer's declaration for EMC**. Failure to follow these instructions may cause the instrument to malfunction.
- The instrument cannot be operated under oxygen enriched environment.

MR Conditional

Non-clinical testing has demonstrated the implantable staples are MR Conditional. A patient with the staples can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3.0-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm(40-T/m)
- Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 2- W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.
- Under the scan conditions defined, the Staple is expected to produce a maximum temperature rise of 1.8°C after 15-minutes of continuous scanning (i.e., per pulse sequence).
- In the non-clinical testing, the image artifact caused by the Staple extends approximately 3-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

3. Device description

3.1 Description of the device

Endo RLC xxx and Endo SRC xxx and Endo AFT xxx are six staggered rows of titanium staples, three on either side of the cut line. The Staplers have staple lines that are approximately 45 mm and 60mm long and cut lines that are 41 mm and 56 mm long respectively. The shaft can rotate freely in both directions. The distal portion can be articulated left or right to facilitate lateral access to the operative site. The Max Articulation angle is not less than 45°.

ID xxx are sterile, single patient use Instrument that, when used with iReach Omnia Staplers Powered Articulating Staplers, can simultaneously cut and staple tissue. There are six staggered rows of staples, three on either side of the cut line.

The Instrument is safe and applicable to the general population, including adults and children.

The staple of Single Use Loading Units for Endoscopic Linear Cutting Staplers and Reloads are non-active implant material.

The instrument modes see Tabel-1 in this file.

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

Previous Device information

Endoscopic Linear Cutting Staplers and Single Use Loading Units for Endoscopic Linear Cutting Staplers (ENDO RLC Series). It was the first generation of ENDO products, Obtained CE certificate in 2016. ENDO SRC Series Devices belong to the second generation of products. ENDO AFT Is a new model of ENDO SRC. REC is the third generation of ENDO products, ID is a new SULU model of the third generation of products, are almost identical to ENDO RLC in structure, materials of parts and same in function mechanism, same in packaging, Same in main manufacturing process, same in method and storage. There are differences in product details. Details reference Tabel-1 in this file.

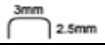
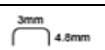
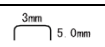
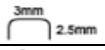
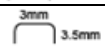
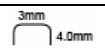
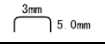
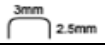
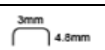
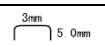
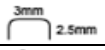
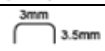
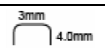
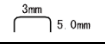
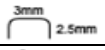
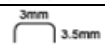
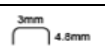
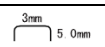
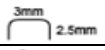
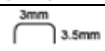
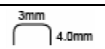
3.3 Description of any accessories which are intended to be used in combination with the device

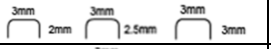
Accessories: There are no accessories of Single Use Loading Units for Linear Cutting Staplers and Reload Units.

3.4 Description of any other devices and products which are intended to be used in combination with the device

Endo RLC xxx and Endo SRC xxx and Endo AFT xxx are intended to be used with the device of Endoscopic Linear Cutting Staplers (Endo RLC xxx and Endo SRC xxx and REC xxx) which manufact in Reach Surgical, Inc. and different diameter of Trocar, and Endoscopic when used in the operation, the Endoscopic in operation was no special requirements when used together. Combination details as the list:

Stapler Product Codes	Reload Product Codes	Staple Line Length	Color	Open Staple Height	Closed Staple Height
ENDO RLC ENDO RLCS ENDO RLCL	ENDO RLC4525L	45mm	White	2.5 mm	1.0mm
	ENDO RLC4535L	45mm	Blue	3.5 mm	1.5mm
	ENDO RLC4548L	45mm	Green	4.8 mm	2.0mm

Stapler Product Codes	Reload Product Codes	Staple Line Length	Color	Open Staple Height	Closed Staple Height
ENDO SRC ENDO SRCS ENDO SRCL	ENDO RLC6025L	60mm	White	2.5 mm	1.0mm
	ENDO RLC6035L	60mm	Blue	3.5 mm	1.5mm
	ENDO RLC6040L	60mm	Gold	4.0 mm	1.75mm
	ENDO RLC6048L	60mm	Green	4.8 mm	2.0mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO RLC4525R	45mm	White	2.5 mm	1.0mm
	ENDO RLC4535R	45mm	Blue	3.5 mm	1.5 mm
	ENDO RLC4548R	45mm	Green	4.8 mm	2.0 mm
	ENDO RLC6025R	60mm	White	2.5 mm	1.0mm
	ENDO RLC6035R	60mm	Blue	3.5 mm	1.5 mm
	ENDO RLC6040R	60mm	Gold	4.0 mm	1.75mm
	ENDO RLC6048R	60mm	Green	4.8 mm	2.0 mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525L	45mm	White		1.0mm
	ENDO SRC4535L	45mm	Blue		1.5mm
	ENDO SRC4548L	45mm	Green		2.0 mm
	ENDO SRC4550L	45mm	Black		2.2 mm
	ENDO SRC6025L	60mm	White		1.0mm
	ENDO SRC6035L	60mm	Blue		1.5mm
	ENDO SRC6040L	60mm	Gold		1.75mm
	ENDO SRC6048L	60mm	Green		2.0mm
	ENDO SRC6050L	60mm	Black		2.2 mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525R	45mm	White		1.0mm
	ENDO SRC4535R	45mm	Blue		1.5mm
	ENDO SRC4548R	45mm	Green		2.0 mm
	ENDO SRC4550R	45mm	Black		2.2 mm
	ENDO SRC6025R	60mm	White		1.0mm
	ENDO SRC6035R	60mm	Blue		1.5mm
	ENDO SRC6040R	60mm	Gold		1.75mm
	ENDO SRC6048R	60mm	Green		2.0mm
	ENDO SRC6050R	60mm	Black		2.2 mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525BL	45mm	White		1.0mm
	ENDO SRC4535BL	45mm	Blue		1.5mm
	ENDO SRC4548BL	45mm	Green		2.0 mm
	ENDO SRC4550BL	45mm	Black		2.2 mm
	ENDO SRC6025BL	60mm	White		1.0mm
	ENDO SRC6035BL	60mm	Blue		1.5mm
	ENDO SRC6040BL	60mm	Gold		1.75mm

Stapler Product Codes	Reload Product Codes	Staple Line Length	Color	Open Staple Height	Closed Staple Height
	ENDO SRC6048BL	60mm	Green		2.0mm
	ENDO SRC6050BL	60mm	Black		2.2 mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525BR	45mm	White		1.0mm
	ENDO SRC4535BR	45mm	Blue		1.5mm
	ENDO SRC4548BR	45mm	Green		2.0 mm
	ENDO SRC4550BR	45mm	Black		2.2 mm
	ENDO SRC6025BR	60mm	White		1.0mm
	ENDO SRC6035BR	60mm	Blue		1.5mm
	ENDO SRC6040BR	60mm	Gold		1.75mm
	ENDO SRC6048BR	60mm	Green		2.0mm
	ENDO SRC6050BR	60mm	Black		2.2 mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO AFT45TNR	45mm	Tan		0.75mm,1.0mm,1.25mm
	ENDO AFT45PLR	45mm	Purple		1.25mm,1.5mm,1.75mm
	ENDO AFT45BKR	45mm	Black		1.75mm,2.0mm,2.2mm
	ENDO AFT60TNR	60mm	Tan		0.75mm,1.0mm,1.25mm
	ENDO AFT60PLR	60mm	Purple		1.25mm,1.5mm,1.75mm
	ENDO AFT60BKR	60mm	Black		1.75mm,2.0mm,2.2mm
	ENDO AFT45TNBR	45mm	Tan		0.75mm,1.0mm,1.25mm
	ENDO AFT45PLBR	45mm	Purple		1.25mm,1.5mm,1.75mm
	ENDO AFT60TNBR	60mm	Tan		0.75mm,1.0mm,1.25mm
	ENDO AFT60PLBR	60mm	Purple		1.25mm,1.5mm,1.75mm

Product Code	Staple Line Length	Trocar Compatibility	Description	Shaft Length	Total Length
REC60AL	60 mm	12mm	Long Articulating	448mm	715 mm
REC45AL	45 mm	12mm	Long Articulating	432mm	700 mm
REC60A	60 mm	12mm	Articulating	348mm	615 mm
REC45A	45 mm	12mm	Articulating	332mm	600 mm
REC60AS	60 mm	12mm	Short Articulating	298mm	565 mm
REC45AS	45 mm	12mm	Short Articulating	282mm	550 mm
REC60BAL	60 mm	12mm	Long Articulating	459mm	727 mm
REC45BAL	45 mm	12mm	Long Articulating	443mm	712 mm
REC60BA	60 mm	12mm	Articulating	359mm	627 mm
REC45BA	45 mm	12mm	Articulating	343mm	612 mm
REC60BAS	60 mm	12mm	Short Articulating	309mm	577 mm
REC45BAS	45 mm	12mm	Short Articulating	293mm	562 mm

ID xxx is only compatible with the Powered Articulating Staplers by the manufacturer. When the Instrument is used for minimally invasive surgery, a trocar is needed.

Product Code	Description	Instrument Length (mm)	Shaft Length (mm)
IDL	Long Articulating	500	255
IDM	Medium Articulating	400	155
IDS	Short Articulating	330	85

4. Risks and warnings

4.1 Residual risks and undesirable effects

Potential complications related to the use of the Instrument include hemorrhage, tissue injury, introduction of non-sterile surface or pathogen transfer, inflammatory or accidental tissue reaction, electrical shock, property damage or environmental damage. In addition, incomplete suture, inability to cut or Instrument damage may cause accidental injury, prolongation of operation time or change of operation method.

4.2 Warnings and Precautions

4.2.1 Warning- Endo RLC xxx and Endo SRC xxx and Endo AFT xxx:

1. The Endoscopic Linear Cutting Staplers with Single Use Loading Units 2.5 mm SULU cannot be used on any tissue that is compressed to less than 1.0 mm in thickness, or that cannot be comfortably compressed to 1.5 mm or on aorta.
2. The Endoscopic Linear Cutting Staplers with Single Use Loading Units 3.5 mm SULU cannot be used on any tissue that is compressed to less than 1.5 mm in thickness, or that cannot be comfortably compressed to 2.0 mm or on aorta.
3. The Endoscopic Linear Cutting Staplers with Single Use Loading Units 4.0 mm SULU cannot be used on any tissue that is compressed to less than 1.7mm in thickness, or that cannot be comfortably compressed to 2.2mm or on aorta.
4. The Endoscopic Linear Cutting Staplers with Single Use Loading Units 4.8 mm SULU cannot be used on any tissue that can be compressed to less than 2.0 mm in thickness, or that

cannot be comfortably compressed to 2.5mm or on aorta.

5. The Endoscopic Linear Cutting Staplers with Single Use Loading Units 5.0mm SULU cannot be used on any tissue that can be compressed to less than 2.2 mm in thickness, or that cannot be comfortably compressed to 2.7mm or on aorta.
6. The Endoscopic Linear Cutting Staplers with tan SULU and tan curved tip SULU cannot be used on any tissue that compresses to less than 0.75 mm in thickness, or that cannot comfortably compresses to 1.5 mm or on aorta.
7. The Endoscopic Linear Cutting Staplers with purple SULU and purple curved tip SULU cannot be used on any tissue that compresses to less than 1. 5 mm in thickness, or that cannot comfortably compresses to 2.25 mm or on aorta.
8. The Endoscopic Linear Cutting Staplers with black SULU cannot be used on any tissue that compresses to less than 2.25 mm in thickness, or that cannot comfortably compresses to 3.0 mm or on aorta.
9. The Endoscopic Linear Cutting Staplers with Single Use Loading Units cannot be used on liver, spleen or similar tissue that compression may lead to destructive effects.
10. The Endoscopic Linear Cutting Staplers with Single Use Loading Units cannot be used on the patients who are undergoing anticoagulation therapy.
11. The Endoscopic Linear Cutting Staplers with Single Use Loading Units cannot be used on the tissues whose airproof or integrity of staple line cannot be ensured. Reinforcement material may be used if the Endoscopic Linear Cutting Staplers with Single Use Loading Units should be used.

4.2.2 Precautions: Endo RLC xxx and Endo SRC xxx and Endo AFT xxx

1. Preoperative radiotherapy can result in tissue changes, which may cause the tissue thickness exceeds the indicated range for the selected staple size. Careful considerations should be given to any pre-surgical treatment and select the staple size correspondingly.
2. Always inspect the thickness of the tissue and select an appropriate staple size before the application of the Endoscopic Linear Cutting Staplers with Single Use Loading Units. When choosing the SULU of proper staple height, always consider the combined thickness of the tissue and of any staple line reinforcement material.

3. When the Endoscopic Linear Cutting Staplers with Single Use Loading Units is used with a 4.8 mm and 5.0mm SULU, a black (4.0mm,4.5mm,5.0mm) SULU, the instrument MUST be introduced through a 15.5 mm trocar. A smaller size trocar will not be suitable for the 4.8, 5.0 SULU and a black SULU.
4. Always close the jaw of Endoscopic Linear Cutting Staplers with Single Use Loading Units before introducing and removing the instrument from the trocar sleeve.
5. After firing, the staple line should always be inspected for hemostasis. Minor bleeding can be controlled by electrocautery or manual sutures.
6. Placing tissue proximal to the tissue stops (on the SULU) may cause instrument malfunction. Tissue extending beyond the cut mark will not be transected.
7. When the stapler is used more than once in a SINGLE surgical procedure, make sure to remove the empty SULU and SULU a new one. A safety interlock will prevent an empty SULU from being fired a second time. Please do not try to override the safety interlock.
8. Make sure that no obstructions, such as clips, are incorporated into the instrument jaw when positioning the instrument on the application site. Fire the instrument over an obstruction may result in incomplete cutting and/or improper staple formations.
9. Endoscopic procedures should be performed by physicians who have adequate training on endoscopic techniques. Before the performance of any endoscopic procedures, consult the medical literature relating to techniques, complications and hazards.
10. The SULU can be opened within the body cavity only when the anvil is completely visible.
11. When a staple line reinforcement material is used, follow the instructions provided by the manufacturer of the reinforcement material, because the performance of the instrument may be affected by using these materials.
12. The Endoscopic Linear Cutting Staplers and Single Use Loading Units for Endoscopic Linear Cutting Staplers are provided STERILE and intended for use in a SINGLE procedure only. PLEASE DISCARD AFTER USE AND DO NOT RESTERILIZE.
13. Please do not try to load a SULU while the ring handle is squeezed.
14. In laser and electrosurgical procedures, a thorough understanding of the principles is essential to avoid shock and burn hazards to patient and operator(s), and damage to the instrument.
15. The Endoscopic Linear Cutting Staplers and Single Use Loading Units for Endoscopic Linear Cutting Staplers are sterilized with EO. The period of validity is 5 years and has been marked on each layer of product package. PLEASE DO NOT use an expired product clinically.
16. After use, the Endoscopic Linear Cutting Staplers and Single Use Loading Units for Endoscopic Linear Cutting Staplers should be disposed of in appropriate recycling or trash bin.
17. When manipulating the tissue with the curved tip SULU, avoid exerting excessive pressure

on fragile structure with the curved tip of the device.

4.2.3 Warnings and Precautions -Endo REC xxx

1. Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or staple line disruption.
2. Do not load the instrument more than 12 times for a maximum of 12 firings per instrument.
3. Minimally invasive and stapling procedures should be performed only by persons having adequate training and familiarity with the techniques. Consult relative medical literature for techniques, complications, and hazards prior to performing any minimally invasive procedure.
4. When minimally invasive instruments and accessories from different manufacturers are used together in a procedure, verify compatibility prior to initiation of the procedure.
5. When using other technologies (e.g., electrosurgery devices), observe the precautions suggested by the manufacturer to avoid the hazards associated with their use.
6. The Stapler instruments may only be used with ENDO REACH REC Staplers.
7. After removing the Staple Retaining Cap, observe the surface of each new reload. The Reload must be replaced with another Reload if any colored driver is visible because the Reload may not contain staples.
8. For insertion and removal of instruments, the jaws of the instrument must be straight, in line with the Shaft of the instrument. Failure to have the instrument jaws in the straight position will result in difficult insertion or withdrawal of the instrument and may result in damage to the instrument or trocar.
9. When placing the instrument through the trocar or incision, avoid inadvertently pulling the Firing Trigger. If the instrument is partially or completely fired, it will need to be reloaded before using on tissue. If the instrument is partially fired, remove the instrument and replace the Reload.
10. The instrument can achieve a maximum articulation angle of 45°. When the force increases, it indicates the maximum angle has been reached.
11. Ensure that the tissue lies flat and is positioned properly between the jaws. Any “bunching” of tissue along the Reload, particularly near the Proximal Mark of the jaws, may result in an incomplete staple line. The Cut Mark on the Reload Jaw designates the end of the staple line.
12. When positioning the jaws on the application site, ensure that no obstructions such as clips, stents, guide wires, etc. are within the instrument jaws. Firing over an obstruction may result in incomplete cutting action, improperly formed staples, and/or inability to open the instrument jaws.
13. Ensure that tissue has not squeezed (extended) proximal to the Proximal Mark on the instrument. Tissue forced into the instrument proximal to the Proximal Mark may be transected without staples. When firing across thick tissue, holding the jaws in place for 15

seconds after closing and prior to firing may result in better compression and staple formation.

14. If the clamping mechanism becomes inoperative and the jaws do not clamp on tissue, do not fire the instrument. Remove and do not continue to use the instrument.
15. The instrument should be replaced if it does not fire smoothly or the firing mechanism becomes inoperative. Attempting to force the device to complete the firing stroke under very high load may cause a snap sound and a sudden decrease in force to fire; if this occurs, discontinue the use of the instrument and thoroughly inspect the staple line integrity.
16. Examine the staple lines for pneumostasis/hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.
17. Prior to reloading the instrument, hold the instrument in a vertical position, with Anvil Jaw and Reload Jaw completely submerged in sterile solution. Swish vigorously and then wipe the inside and outside surfaces of the Anvil Jaw and Reload Jaw to clean any unused staples from the instrument. Do not use the instrument until it has been visually inspected to confirm that there are no staples on the Anvil Jaw or Reload Jaw.
18. Gently pull the instrument away from the transected tissue and ensure it is released from the jaws before removing.
19. When selecting the Reload, careful consideration should be given to existing pathologic conditions as well as any pre-surgical treatment, such as radiotherapy, that the patient may have undergone. Certain conditions or preoperative treatments may cause change in tissue thickness that would exceed the indicated range of tissue thickness for the standard choice of Reload.
20. When dividing major vascular structures, be sure to adhere to the basic surgical principle of proximal and distal control.
21. If it needs to be used together with bipolar electrosurgical instrument, please pay attention to protect the anastomosis.
22. Short instrument can be used for thoracoscopic surgery and open surgery.
23. Do not modify this equipment without authorization from the manufacturer.
24. Instruments or devices in contact with body fluids may require special disposal to prevent biological contamination.
25. This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or re sterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or re sterilization of single use devices may create a risk of contamination and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

4.2.4 Warnings and Precautions -ID xxx

1. Examine the shipping carton and Instrument for signs of shipping damage. Note any shortages, breakage, or apparent damage, retain the evidence, notify Customer Service or Distributor immediately and replace with a new Instrument. Do not use a damaged product.
2. Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
3. Instruments for minimally invasive procedure may vary in diameter from manufacturer to manufacturer. When such Instruments and accessories from different manufacturers are employed together in a procedure, verify their compatibility prior to procedure.
4. Do not use the Instrument if the shaft is visibly bent.
5. Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
6. The Instrument must be disposed after procedure once the package is opened.
7. The Instrument is designed, inspected, and manufactured for single procedure only. Do not reuse, reprocess or re sterilize the Instrument as it may compromise the structural integrity of the Instrument, and/or lead to Instrument failure that in turn may result in patient injury, illness, or death.
8. Reusing the Instrument may create risk of contamination, infection, or cross-infection, including, but not limited to, the transmission of infectious diseases, which may lead to injury, illness, or death.
9. After removing the Shipping Wedge, observe the surface of the Reload. The Reload Units must be replaced with another Reload Units if any staple tray is visible. (If staple tray is visible, the Reload may not contain staples.)
10. Do not articulate when the jaws are closed.
11. When selecting the Reload Units, careful consideration should be given to existing pathologic conditions as well as any pre-surgical treatment, such as radiotherapy, that the

patient may have undergone. Certain conditions or preoperative treatments may cause change in tissue thickness that would exceed the indicated range of tissue thickness for the standard choice of Reload Units.

12. Avoid using the Instrument adjacent to or stacked with another equipment. If it is necessary to use the Instrument adjacent or stacked with another Instrument, pay attention, and notice any abnormalities.
13. Do not modify the Instrument without authorization from the manufacturer.
14. Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this Instrument and result in improper function.
15. The Instrument cannot be operated under oxygen enriched environment.
16. In case of any adverse event related to the Instrument, please communicate with the manufacturer through Reachquality@reachsurgical.com.

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

There have been no field safety corrective actions associated with the instrument, and no other relevant aspects of safety to be discussed.

5. Summary of clinical evaluation and post-marketing clinical follow-up related data

The clinical evaluation is based on a comprehensive analysis of available pre-market and post-market clinical data relevant to the intended purpose of the device in question, including clinical performance data and clinical safety data.

There are discrete stages in performing a clinical evaluation:

CER was conducted to assess the safety and performance of the Staplers.

A review of published clinical data, post-market surveillance data, and public vigilance databases, in conjunction with the product risk analyses, we found there is no death or fatal injury event occurred yet. No recall or advisory notice related to the instruments. It demonstrates that the use of this product by medical professionals does not pose any undue risks to patients and that the

instruments can be used safely and effectively for their intended use.

Further, this clinical evaluation report provides evidence that the benefits of use outweigh anticipated or reported risks to the patients for the instruments. The staplers have a good effect on performance in general, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses. It can successfully resection or anastomoses the target tissue, while provides a high probability of shorter operative time, lower blood loss/transfusion rates, and reduced postoperative complications among patients compared to manual cutting. Any risks identified in this evaluation have been adequately addressed in the risk management documentation.

Based on a review of current and generally accepted options for the intended use of the instruments, the System aligns with the state of the art for relevant clinical use. And there is no novelty or brand new technology introduced in the design phase of The instruments. This product is considered to base on well-established technology and not novel.

Based on the analysis of intended use, internal and external clinical data, and safety/performance analysis, it is concluded that the instruments are compliant with MDR General Safety and Performance Requirements.

The System has been designed and manufactured such that the System will not compromise the clinical condition or the safety of patients，or the safety and health of users and/or，other applicable persons when The Staplers is used under the conditions and for the purposes intended. The risks associated with the System are identified and mitigated as far as possible to an acceptable level when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety by meeting applicable standards and/or specifications.

The System has achieved the specified performances intended by REACH and was designed manufactured and packed such that they are suitable for the intended functions.

The System has thoroughly evaluated that undesirable side effects constitute an acceptable risk when weighed against the intended performances.

The device implements and maintains a PMS system that routinely monitors the clinical performance and clinical safety of the device as part of its quality management system. PMCF is

a continuous process that reviews and updates the clinical evaluation during the post-market phase. According to PMCF confirming the safety and performance, including the clinical benefit of the device throughout its expected lifetime:

C1. Post-market surveillance

The instruments family adverse complaints analysis results from January 01, 2021 to January 01, 2022.there were no death, no serious adverse events during this period. And there were no reports of death across the public vigilance databases searched of the Reach Surgical Staplers. Post-market surveillance which included internal complaint reporting and public vigilance data showed the adverse events of the instruments family staplers in overseas markets have all come from the Brazilian market, and the probability of occurrence is 0.01% since 2018. And all adverse events were non-serious injury events. Since the increase of usage in the Brazilian market in 2018, the complaint rate has shown an upward trend. After product quality has been improved, the complaint rate has dropped to 0.12%.

In a search of public vigilance databases, there is no death or fatal injury event occurred. And no recall or advisory notice related to the instruments family staplers were found.

For internal complaints and public vigilance reports review against the potential hazards and harms addressed in the Endo XXX PSUR (KF-H68-LC-10-202203) confirmed that no new or unknown hazards were identified for these devices.

C2. Screening of scientific literature and other sources of clinical data

We searched the clinical literature data on the product since its launched, and collected a total of 17 articles related to the instruments and SULUS, overall level of evidence per the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence was good, including 5 randomized controlled trials in level II, 8 case-control studies in level III, and 4 case-series studies in level IV. There were 5 articles of ENDO RLC Stapler, 2 articles of ENDO REC Stapler, 10 articles of other size of SULUS for the instruments.

A total of 1196 patients were included in these 17 articles related to the instruments family and SULUS. These included 6 studies of rectal cancer; 7 studies of digestive-related diseases, such as stomach, intestines, and esophagus; 2 studies of pulmonary diseases; 1 study of splenectomy;

and 1 study of Crohn's disease. In these studies, there were two intra-operative minor incidents connected to the closure mechanism that had been initiated too quickly (the cartridge had to be changed without further prejudice), but no injury was caused by this. Another two patients presented with enterorrhagy, after expectant management, both cases progressed without additional bleeding episodes. The articles did not reveal significant differences in the use, and complication rate of handling of the REACH stapler compared with the other two brands studied, therefore, the cost-effectiveness of the REACH product should be considered. While no stapler-related mortality was observed in those articles of the staplers. And there is no serious adverse events related to the stapler were reported in those studies. It's fully proved the safety and effectiveness of the instruments family in clinical use.

The clinical studies demonstrated use of the instruments family as intended. It confirmed that the benefits associated with the intended use of the system outweighs the risks. It can improve the surgery, application in general, gynecological, pediatric and thoracic surgery for resection, transection, and creation of anastomoses with a good effect of safety and performance.

C3. Surveys

A questionnaire has been sent to the surgeons to evaluate properties concerning resection/transection or creation of anastomoses functions, and ergonomic design of The instruments. Through the analysis of the results obtained by the doctor's investigation, the doctor's operation as a whole meets the requirements of product use, and the doctor is satisfied with the use of Reach's product as a whole. Note: Due to the different listings of products in Europe, the number of survey samples for each product is different. Details data analysis reference sub-attachment file KF-000-LC-11-2021-06 report.

5.1 Summary of clinical data related to equivalent device

According to the comparison, the device under evaluation is equivalence with the predicate device in the following aspects:

Same clinical significance: two devices used for the same clinical condition or purpose, at the same site in the body, in a similar population; have the same relevant critical performance according to the expected clinical effect for the specific intended use.

Same technical: two devices were designed under the same principle, same mechanical structure, same testing requirements; and used under the same conditions; have the same theory, specifications, and similar principles of operation.

Same biocompatibility: two devices used similar materials which contact people, and with the same human tissues, also all were validated according to EN ISO 10993 series standard.

In summary, the Endoscopic Linear Cutting Staplers & Single Use Loading Units for Endoscopic Linear Cutting Staplers used a similar design concept, product structure, and manufacturing technology. No brand new technology was introduced in the design phase of the product. And compared with the existing technologies there is no novelty in the product under evaluation. Therefore it was anticipated that using the Endoscopic Linear Cutting Staplers & Single Use Loading Units for Endoscopic Linear Cutting Staplers would not pose any new risks compared with the existing device.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking

As The instruments have registered in EU、FDA and NMPA for many years, it has one pre-market clinical study in China, beyond that the evaluation of the safety and performance is based on clinical date and clinical literature of itself and similar devices.

One pre-market clinical study was performed in China on the ENDO REACH Stapler of ENDO RLC Series in 2009. While the results were collected and submitted to the NMPA to support supported products coming to market in China. This study was conducted in accordance with the ethical principles originating in the Declaration of Helsinki. The study was conducted at two centers, with separate randomization. After approval by the Ethical Committee of Huaxi Hospital Sichuan University and 1st Affiliated Hospital, Medical College, Zhejiang University, and the investigators thoroughly introduced the objective, procedure, acquired benefit and possible risk of the clinical trial to the patients or their trustors with written form, and asked the patient to sign the Informed Consent.

This was a randomized controlled trial with ENDO REACH Stapler in the observation group and a similar imported stapler in the control group. The target cases were the patients that need open or endoscopic surgery on lung, bronchia, stomach or intestinal resection, transaction and suture. No drop, no lost or no withdrawal case in this trial.

The clinical investigation showed the Endoscopic linear cutter has not different from those imported ones in suture reliability and post-operational complications (suture bleeding, suture fistula, suture gas leakage etc.), which indicated that Endoscopic linear cutter reached the same level of imported ones and is a safe and effective stapler for digestive tract.

5.3 Summary of clinical data from other sources

According to the description and problems of PMS purpose in PMS plan and the principle of focusing on the continuous safety and effectiveness of products in post-marketing testing, summarize the PMS data and analysis summarized there is no new risk be found and the device is safe and effective.

In addition, we searched the clinical literature data on the product since its launch. We collected a total of 16 articles related to the instruments and SULUS, with comprised a good level of evidence. While no death events or serious adverse events related to the stapler were reported in those studies, The instruments have been used in a clinical application with a good effect on performance for resection, transection, and creation of anastomoses in thoracic, abdominal, gynecological surgeries. It's fully proved the safety and effectiveness of Instruments s in clinical use.

5.4 An overall summary of the clinical performance and safety

For this evaluation, clinical data held by Reach Surgical, Inc comprised pre-clinical testing and post-market surveillance data.

From all the data reviewed, the sales figures of the instruments are 122,691 in 2021, there is no death or fatal injury event occurred yet. It was anticipated that using the instruments would not pose any new risks compared with the existing device.

As demonstrated by the clinical evaluation, The Staplers can improve the surgery, application in open and minimally invasive surgeries including thoracic, abdominal, gynecological, urological surgeries for resection, transection, and creation of anastomoses with a good effect on safety and performance, According to the literature search, we analyzed the collected literature and proved our claims that The Staplers have been associated with reducing surgical time compared to manual sewing techniques among patients in general procedures and fewer postoperative complication, such as short operative time, less intraoperative blood loss, etc.

Post-market surveillance included internal complaint reporting and public vigilance data. For internal complaint reporting, in total, for the subject devices during the reporting period, no death or serious injuries were reported. A total of 95% of the failures were caused by doctors' failure to

operate in accordance with the instructions, the training of doctors should be strengthened. Since 2018, the adverse events of the instruments in overseas markets have all come from the Brazilian market, and the probability of occurrence is 0.01%. And all adverse events were non-serious injury events. In a search of public vigilance databases, there is no death or fatal injury event occurred. And no recall or advisory notice related to the instruments were found.

We searched the clinical literature data on the product since it's launched and collected a total of 17 articles with comprised a good level of evidence related to the instruments and SULUS. No stapler-related mortality was observed in those articles of the instruments. There were two intra-operative minor incidents connected to the closure mechanism that had been initiated too quickly (the cartridge had to be changed without further prejudice), but no injury was caused by this. Another two patients presented with enterorrhagy after expectant management, both cases progressed without additional bleeding episodes. The articles did not reveal significant differences in the use, and complication rate of handling of the REACH stapler compared with the other two brands studied, therefore, the cost-effectiveness of the REACH product should be considered.

Based on this extensive review, we believe that Endoscopic Linear Cutting Staplers & Single Use Loading Units for Endoscopic Linear Cutting Staplers is designed and manufactured in such a way that, when used by trained persons under the conditions and for the purpose intended, the product will not compromise the clinical condition(s) and safety of patients, the safety and health of users, or safety and health of other persons.

5.5 Ongoing or planned post-market clinical follow-up

Considering that the device directly contacts human tissue, it is necessary to have a clinical following-up evaluation, the device is planned to make the PMCF at least one year, the First time is in Mar-Apr, 2022, and the next PMCF update is in Mar-Apr, 2023.

6. Possible diagnostic or therapeutic alternatives

The devices and surgical techniques available for thoracic, abdominal, gynecological, urological surgeries of resection, transection, and creation of anastomoses are developed and evolved

rapidly with the improvement of material science and engineering science. Besides the manual sutures, there are several alternative therapies in related fields including electrocautery devices, ultrasonic scalpel/shear, etc.

After firing by using the stapler in surgical procedures, the staple line should always be inspected for hemostasis. Minor bleeding can be controlled by electrocautery or manual sutures.

Eventually, the surgeon should select anastomotic materials according to the nutritional status of the patient, the nature of the operation, the wound site, and the characteristics of the suture tissue.

7. Suggested profile and training for users

IIFU content that minimally invasive and stapling procedures should be performed only by persons who had formal education in the relevant field and familiarity with the techniques.

Consult relative medical literature for techniques, complications, and hazards prior to performing any minimally invasive procedure.

8. Reference to any harmonized standards and CS applied

Standard No.	Standard Name
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 5832-1:2019	Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel
EN ISO 5832-2:2018	Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2:2018)
EN ISO 5832-3:2016	Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy（EQV ISO 5832-3:2016）
EN ISO 14630：2012	Non-active surgical implants - General requirements (ISO 14630:2012
ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
EN ISO 7153-1：2016	Surgical instruments: Metallic materials. Stainless steel
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)

EN 556-1:2001+AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE”- Part 1: Requirements for terminally sterilized medical devices
EN ISO 11737-1:2020	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2020)
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
EN ISO 11138-1:2017	Sterilization of health care products – Biological indicators – Part 1: General requirements (ISO 11138-1:2017)
EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-7:2008+AC:2009	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008/Cor 1:2009)
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017 EQV)
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems ((ISO 11607-1:2019)
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006, including Amd 1:2019)
CEN ISO TR 20416:2020	Medical devices - Post-market surveillance for manufacturers

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
KF-H68-SZ-23 Issue Rev: 1.0	10-Jan-2023	Initial Release	☑Yes Validation language: EN language □No