

Device Schedule:

Intended Purpose as per the Instructions for Use:

OverStitch:

The OverStitch™ Endoscopic Suture System is indicated for the endoscopic placement of anchor-sutures. Anchor-sutures can be placed for defect closure (e.g. perforation, ESD/EMR and fistula/leak), stent fixation to reduce migration rates in the upper GI tract, endoscopic sleeve gastropasty, and transoral outlet reduction.

Risk Classification: Class IIb, Implantable

Basic UDI-DI: 081195502381337C8

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification
OverStitch™ Suture Cinch	CNH-G01-000	MDN 1104	Class IIb, Implantable

Intended Purpose as per the Instructions for Use:

X-Tack:

The X-Tack™ System is intended for approximation of soft tissue in minimally invasive gastroenterology procedures (e.g. closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks).

The X-Tack™ System is not intended for hemostasis of acute bleeding ulcers

Risk Classification: Class IIb, Implantable

Basic UDI-DI: 081195502381337C8

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification
OverStitch™ Suture Cinch	CNH-G01-000	MDN 1104	Class IIb, Implantable
Suture Cinch Long	CNH-C01-213-L	MDN 1104	Class IIb, Implantable