EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 756446 R000

Manufacturer: Apollo Endosurgery, Inc.

Address:
1120 S. Capital of Texas Hwy
Bldg 1, Suite 300
Austin
Texas
78746
USA

Single Registration Number: US-MF-000003488

EU Authorised Representative: Emergo Europe B.V.

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-11-16**

Current Issue Date: **2023-10-30**

Starting Validity Date: **2023-10-30**

Expiry Date: **2027-11-15**

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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 gastroplasty, 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

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-11-16	3507242	Issued
2023-08-21	30001475	Amended – Minor update of Legal Manufacturer Address to include "S." Amended – Change of authorized representative address to Westervoortsedijk 60 6827 AT Arnhem The Netherlands
Current	3917283	Supplemented – addition of Suture Cinch Long

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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