EU Technical Documentation Assessment Certificate

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

MDR 756439 R000

Manufacturer: Apollo Endosurgery, Inc.

Address:
1120 S. Capital of Texas Hwy
Building 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: **2023-10-30**

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

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

Expiry Date: **2028-10-29**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

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: 0811955022319131046

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**
X-Tack Endoscopic HeliX Tacking System	XTACK-160-H	MDN 1104	Class IIb, Implantable
X-Tack Endoscopic HeliX Tacking System	XTACK-235-H	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
Current	3507252	Issued

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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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