EU Technical Documentation Assessment Certificate

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

MDR 779631 R000

Manufacturer: Apollo Endosurgery, Inc.

Address:
1120 Capital of Texas Highway
Building 1, Suite 300
Austin
Texas
78746
USA

Single Registration Number: US-MF-000003488

EU Authorised Representative: Emergo Europe B.V.

Address:
Prinsessegracht 20
2514 AP The Hague
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: **2022-11-16**

Starting Validity Date: **2022-11-16**

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

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Device Schedule:

Intended Purpose as per the Instructions for Use:

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: 081195502182019201759Z

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification
OverStitch™ 2-0 Polypropylene Suture	PLY-G02-020-APL	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	3507218	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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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.