EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 756134 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 examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: Class III and Class IIb devices

Class IIb, Implantable	Intended purpose
ORBERA365™ Intragastric Balloon System	See MDR 756442
BIB™ Intragastric Balloon System	See MDR 756443
OverStitch™ 2-0 Polypropylene Suture	See MDR 779631
OverStitch™ Suture Cinch	See MDR 756446
X-Tack™ Endoscopic HeliX Tacking System	See MDR 756439

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Suture Devices – Other (Needle Holder)	Class IIa
Suture Devices – Other (Tissue Grasper)	Class IIa
Gastrointestinal Tubes - Accessories	Class IIa

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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	3507231	Issued
2023-08-21	30001471	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	3916309	Supplemented – Addition of X-Tack to the Device Schedule Supplemented – Implementation of eIFU only across all products

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