EU Technical Documentation Assessment Certificate

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

MDR 756443 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 BIB™ Intragastric Balloon System is indicated for temporary use in weight-loss therapy for obese patients who have significant health risks related to their obesity and who have failed to achieve and maintain weight loss with a supervised weight-control program

The BIB™ Intragastric Balloon System is indicated for:

- Pre-surgical temporary use for weight loss in obese patients (BMI 40 and above or a BMI of 35 or above with comorbidities) prior to obesity or other surgery, in order to reduce surgical risk.
- Temporary use for weight loss in obese patients (BMI 30-39) who have significant health risks related to their obesity and who have failed to achieve and maintain weight loss with a supervised weight-control program. The BIB System is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of long-term weight-loss maintenance.
- Temporary use for weight loss in obese patients (BMI 40 or above, or BMI 35 or above with comorbidities) who are not candidates for obesity surgery, in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of long-term weight-loss maintenance.
- The maximum placement period for the BIB™ System is 6 months, and it must be removed at that time or earlier.

Risk Classification: Class IIb, Implantable

Basic UDI-DI: 08119550221111114144135S

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**
BIB™ Intragastric Balloon System	B-40800	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	3507251	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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
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