EU Technical Documentation Assessment Certificate

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

MDR 756442 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 ORBERA365™ Intragastric Balloon System is to be used in conjunction with a long-term supervised diet and behaviour modification program designed to increase the possibility of long-term weight loss maintenance.

The ORBERA365™ Intragastric Balloon System is indicated for:

- Temporary use for weight loss in obese patients (BMI 30-50) who failed to achieve and maintain weight loss with a supervised weight-control program.
- Pre-surgical temporary use for weight loss in obese and super obese patients (BMI 40 and above or a BMI of 35 with comorbidities) prior to obesity or other surgery, in order to reduce surgical risk.

The maximum placement period for the ORBERA365™ System is 12 months, and it must be removed at that time or earlier.

Risk Classification: Class IIb, Implantable

Basic UDI-DI: 0811955022111111414135S

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**
ORBERA365™ Intragastric Balloon System	B-50012	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	3507249	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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A Member of the BSI Group of Companies.