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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 667860**
Date: **2020-04-01**
Issued To: **Biosphere Medical SA**
Parc des Nations
Paris Nord 2
383, rue de la Belle Etoile
Roissy-en-France
95700
France

Date	Reference Number	Action
13 March 2019	8676306	First Issue.
14 March 2019	8970525	Traceable to NB 0086.
03 December 2019	3066739	Addition of Embosphere Microspheres in syringe.
Current	8676306	Updated device table to include Embosphere Microspheres in Vial; EmboGold Microspheres in Syringe; EmboCath Plus Infusion MicroCatheters; Tenor Steerable Guidewire; extended scope to include microcatheters and guidewires; added Lake Region Medical Ltd. ,Brivant Limited, and Merit Medical as Subcontractors.

Digitally signed by Ostapciuc Alexandr
Date: 2021.12.20 15:16:17 EET
Reason: MoldSign Signature
Location: Moldova

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TRIBESTAR farm S.R.L. IDNO 1014600033307

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EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 667865**

Issued To: **Biosphere Medical SA**
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In respect of:

Embosphere Microspheres in Syringe

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-12-03** Date: **2019-12-03** Expiry Date: **2024-05-26**

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Supplementary Information to CE 667865

Issued To:

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
S010GH	Embosphere Microspheres in Syringe	50 – 100 µm 1 ml Grey	Embolization of hypervascular tumours and processes, including uterine fibroids, meningiomas etc. Embolization of the prostate arteries for relief of symptoms related to Benign Prostatic Hyperplasia Embolization of arteriovenous malformations Haemostatic embolization	Class III Implant
S110GH		40 – 120 µm 1 ml Orange		
S210GH		100 – 300 µm 1 ml Yellow		
S410GH		300 – 500 µm 1 ml Blue		
S610GH		500 – 700 µm 1 ml Red		

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France

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
S810GH	Embosphere Microspheres in Syringe	700 – 900 µm 1 ml Green	Embolization of hypervascular tumours and processes, including uterine fibroids, meningiomas etc. Embolization of the prostate arteries for relief of symptoms related to Benign Prostatic Hyperplasia Embolization of arteriovenous malformations Haemostatic embolization	Class III Implant
S1010GH		900 – 1200 µm 1 ml Purple		
S020GH		50 – 100 µm 2 ml Grey		
S120GH		40 – 120 µm 2 ml Orange		
S220GH		100 – 300 µm 2 ml Yellow		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
S420GH	Embosphere Microspheres in Syringe	300 – 500 µm 2 ml Blue	Embolization of hypervascular tumours and processes, including uterine fibroids, meningiomas etc. Embolization of the prostate arteries for relief of symptoms related to Benign Prostatic Hyperplasia Embolization of arteriovenous malformations Haemostatic embolization	Class III Implant
S620GH		500 – 700 µm 2 ml Red		
S820GH		700 – 900 µm 2 ml Green		
S1020GH		900 – 1200 µm 2 ml Purple		

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Certificate History

Date	Reference Number	Action
Current	8676556 8676557	Transfer from another Notified Body. Renewal of certificate.

First Issued: **2019-12-03** Date: **2019-12-03** Expiry Date: **2024-05-26**

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