



By Royal Charter

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.

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, 389 Chiswick Park Avenue, Uxbridge, Middlesex, UK. Tel: +44 (0)1895 531100
BSI Group The Netherlands B.V., registered in The Netherlands under 33264284.
A member of BSI Group of Companies.



EC Design-Examination Certificate

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

No.**CE 667865**

Issued To:

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Parc des Nations
Paris Nord 2
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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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Page 1 of 5

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 4700
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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.	Class III Implant
S110GH		40 – 120 µm 1 ml Orange	Embolization of the prostate arteries for relief of symptoms related to Benign Prostatic Hyperplasia	
S210GH		100 – 300 µm 1 ml Yellow	Embolization of arteriovenous malformations	
S410GH		300 – 500 µm 1 ml Blue	Haemostatic embolization	
S610GH		500 – 700 µm 1 ml Red		

First Issued: **2019-12-03**

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Expiry Date: **2024-05-26**

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Page 2 of 5

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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.	Class III Implant
S1010GH		900 – 1200 µm 1 ml Purple	Embolization of the prostate arteries for relief of symptoms related to Benign Prostatic Hyperplasia	
S020GH		50 – 100 µm 2 ml Grey	Embolization of arteriovenous malformations	
S120GH		40 – 120 µm 2 ml Orange	Haemostatic embolization	
S220GH		100 – 300 µm 2 ml Yellow		

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Page 3 of 5

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Issued To:

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.	Class III Implant
S620GH		500 – 700 µm 2 ml Red	Embolization of the prostate arteries for relief of symptoms related to Benign Prostatic Hyperplasia	
S820GH		700 – 900 µm 2 ml Green	Embolization of arteriovenous malformations	
S1020GH		900 – 1200 µm 2 ml Purple	Haemostatic embolization	

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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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Page 5 of 5

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