

## **ATTESTATION CE / EC CERTIFICATE**

**Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System**

**ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux**

*ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices*

**Pour les dispositifs de classe III, un certificat CE de conception est requis**

*For class III devices, a EC design certificate is required*

**Fabricant / Manufacturer**

**Lucas Medical, Inc.**

**1751 South Douglass Rd.**

**Anaheim, CA - 92806 UNITED STATES**

**Catégorie du(des) dispositif(s) / Device(s) category**

**Catheters d'embolectomie, d'occlusion, de thrombectomie, biliaires, d'irrigation et catheters bi-lumen d'irrigation arterielle**

*Embolectomy, occlusion, thrombectomy, biliary and irrigation catheters, bi-lumen arterial irrigation catheters*

**Voir détails sur addendum / See attachment for additional information**

**GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000445-1-I / T000445-2-DOCA, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.**

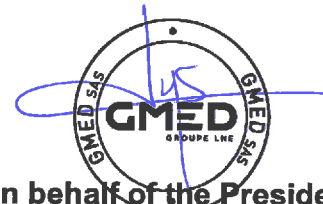
*GMED certifies that, on the basis of the results contained in the file referenced T000445-1-I / T000445-2-DOCA, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4*

**La validité du présent certificat est soumise à une vérification périodique ou imprévue**

**The validity of the certificate is subject to periodic or unexpected verification**

**Début de validité / Effective date : December 18th, 2018 (included)**

**Valable jusqu'au / Expiry date : December 17th, 2021 (included)**



**On behalf of the President**

**Béatrice LYS**

**Technical Director**

**Identification des dispositifs / Identification of devices**

Description du dispositif Médical Medical Device Description	Dénomination Commerciale Catalog reference	Classe du DM MD Class
Biliary Catheter	3F – BIL – 23	Ila
	3F – BIL – 40	Ila
	4F – BIL – 23	Ila
	4F – BIL – 40	Ila
	5F – BIL – 23	Ila
	5F – BIL – 40	Ila
	6F – BIL – 23	Ila
	6F – BIL – 40	Ila
	7F – BIL – 23	Ila
	7F – BIL – 40	Ila
Arterial Embolectomy Catheter	4F- EMB -040	Ila
	4F- EMB -080	Ila
	5F- EMB -040	Ila
	5F- EMB -080	Ila
	6F- EMB -040	Ila
	6F- EMB -080	Ila
	7F- EMB -040	Ila
	7F- EMB -080	Ila
	8F- EMB -040	Ila
	8F- EMB -080	Ila

**GMED 0459**



**On behalf of the President  
 Béatrice LYS  
 Technical Director**

Description du dispositif Médical Medical Device Description	Dénomination Commerciale Catalog reference	Classe du DM MD Class
Arterial Embolectomy Catheter	NL2EMB40	Ila
	NL2EMB60	Ila
	NL2EMB80	Ila
	NL3EMB40	Ila
	NL3EMB80	Ila
	NL4EMB40	Ila
	NL4EMB80	Ila
	NL4EMB100	Ila
	NL5EMB40	Ila
	NL5EMB80	Ila
	NL6EMB40	Ila
	NL6EMB80	Ila
	NL7EMB40	Ila
	NL7EMB80	Ila
	NL2EMB40T	Ila
	NL2EMB60T	Ila
	NL2EMB80T	Ila
	NL3EMB40T	Ila
	NL3EMB80T	Ila
	NL4EMB40T	Ila
	NL4EMB80T	Ila
	NL5EMB40T	Ila
	NL5EMB80T	Ila
	NL6EMB40T	Ila
	NL6EMB80T	Ila
	NL7EMB40T	Ila
	NL7EMB80T	Ila
	Irrigation Catheter	4F – IGR – 80
5F – IGR – 80		Ila
6F – IGR – 80		Ila
7F – IGR – 80		Ila



**GMED 0459**

On behalf of the President  
**Béatrice LYS**  
 Technical Director

Description du dispositif Médical Medical Device Description	Dénomination Commerciale Catalog reference	Classe du DM MD Class
Arterial Bi-Lumen Irrigation Embolectomy Catheter	4F- IRR – 40 – D	Ila
	4F- IRR – 80 – D	Ila
	5F- IRR – 40 – D	Ila
	5F- IRR – 80 – D	Ila
	6F- IRR – 40 – D	Ila
	6F- IRR – 80 – D	Ila
	7F- IRR – 40 – D	Ila
	7F- IRR – 80 – D	Ila
	9F- IRR – 30 – D	Ila
	12F- IRR – 30 – D	Ila
	4F- IRR – 40 – P	Ila
	4F- IRR – 80 – P	Ila
	5F- IRR – 40 – P	Ila
	5F- IRR – 80 – P	Ila
	6F- IRR – 40 – P	Ila
	6F- IRR – 80 – P	Ila
	7F- IRR – 40 – P	Ila
	7F- IRR – 80 – P	Ila
Occlusion Catheter	3F – OCC – 23	Ila
	3F – OCC – 40	Ila
	4F – OCC – 23	Ila
	4F – OCC – 40	Ila
	5F – OCC – 23	Ila
	5F – OCC – 40	Ila
	6F – OCC – 23	Ila
	6F – OCC – 40	Ila
	7F – OCC – 23	Ila
	7F – OCC – 40	Ila

**GMED 0459**



On behalf of the President  
**Béatrice LYS**  
 Technical Director

Description du dispositif Médical Medical Device Description	Dénomination Commerciale Catalog reference	Classe du DM MD Class
Arterial Thrombectomy Catheter	4F-THB-040	Ila
	4F-THB-080	Ila
	5F-THB-040	Ila
	5F-THB-080	Ila
	6F-THB-040	Ila
	6F-THB-080	Ila
	7F-THB-040	Ila
	7F-THB-080	Ila
	8F-THB-040	Ila
	8F-THB-080	Ila

**Ce certificat couvre les activités et les sites suivants :**

*This certificate covers the following activities and sites:*

**Lucas Medical Inc.**  
 1751 South Douglass Rd.  
 Anaheim, CA 92806 - USA

French version: Siege social, distribution, conception, fabrication et contrôle final  
 English version: Headquarters, distribution, design, manufacturing and final control

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**Lucas Medical Inc.**  
 1747 SUITES B,C,D South Douglass Rd,  
 Anaheim, CA 92806 - USA

French version: Distribution, conception, fabrication, et contrôle final  
 English version: Distribution, design, manufacturing and final control

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*2 sites / 2 sites*



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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**