



ATTESTATION / CERTIFICATE N° 35084 rev. 1

Délivrée à Paris le 16 avril 2020

Issued in Paris on April 16th, 2020

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'embolotomie, 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 T000445ER-QA4, 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 T000445ER-QA4, 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 : **April 16th, 2020 (included)**

Valable jusqu'au / Expiry date : **May 26th, 2024 (included)**



On behalf of the President

Béatrice LYS

Technical Director

DocuSigned by:

Béatrice Lys

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GMED_0203-FV-07-2018

GMED - 35084 rev. 1

Renouvelle le certificat 35084-0

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr



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

DocuSigned by:
Béatrice Lys
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Addendum au certificat n° 35084 rev. 1 page 2/4
 Addendum of the certificate n° 35084 rev. 1
 Dossier / File N° T000445ER-QA4

| 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 |



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Béatrice LYS
 Technical Director

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| 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 | |

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