

EC Certificate Full Quality Assurance System: Certificate/Certificat FR96/8324

The management system of / Le système de management de

# COUSIN BIOTECH s.a.s.

8, Rue de l'Abbé Bonpain, 59117 Wervicq-Sud, France

has been assessed and certified as meeting the requirements of  
a été audité et certifié selon les exigences de

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

## Directive 93/42/EEC

Dispositifs médicaux, Annexe II (section 4 exclue)

For the following products / Pour les produits suivants

**The scope of registration appears on page 2 of this certificate.  
Le domaine de certification apparaît en page 2 de ce certificat.**

This certificate is valid from 17 November 2017 until 03 May 2021  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 02 May 2019

Issue 38. Certified since 31 October 1996

Le certificat est valable du 17 novembre 2017 au 03 mai 2021

et reste valide jusqu'à décision satisfaisante à l'issue des audits de suivi.

L'audit de renouvellement doit avoir lieu avant 02 mai 2019

Version 38. Certifié depuis 31 octobre 1996

Certification is based on reports numbered FR/MD 06953  
Cette certification est basée sur les rapports numérotés FR/MD 06953

This is a multi-site certification.

Additional site details are listed on subsequent pages.

Ceci est une certification multisite.

La liste des sites additionnels est mentionnée dans les pages suivantes.

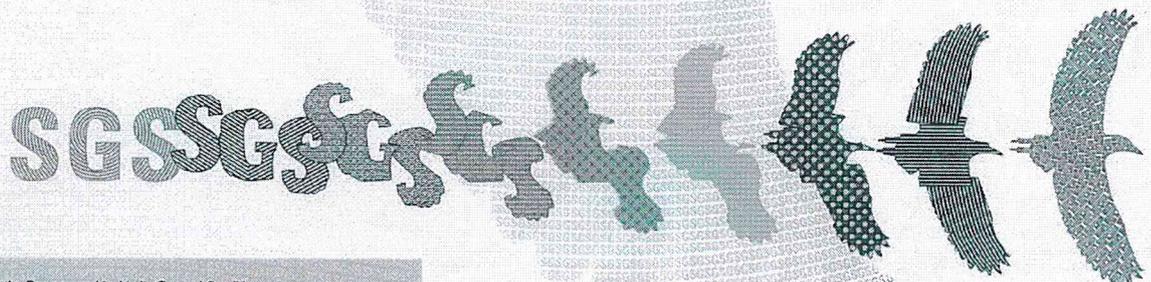
Authorised by/Autorisé par

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SGS CE 02 0315 M4 FR

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## COUSIN BIOTECH s.a.s.

### Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

### Directive 93/42/EEC

Dispositifs médicaux, Annexe II (section 4 exclue)

Issue / Version 38

Detailed scope/Domaine d'activité détaillé

**Non resorbable parietal reinforcement sterile implants (Abdominal plug and meshes and reinforcement plug and meshes abdominal wall); Sterile Adjustable gastric banding; Sterile Non resorbable articular ligaments; Sterile Anchor devices; Sterile Devices for the interspinous space (with spinous support or with laminar support); Sterile Intervertebral prostheses; Sterile Urogenital implants (Suburethral support tape and Implant for the treatment of prolapse); Non-sterile Trial Prosthesis for spinal and visceral surgeries; Sterile ligament system for spine stabilization; Sterile spinal dynamic posterior stabilization devices.**

**Sterile Adhesix® Parietal Reinforcement Meshes with one adhesive side; Sterile Semi Resorbable Meshes, Plugs and Films: 4DMESH®, 4DDOME®, 4D VENTRAL®, Biomesh® CA.B.S.'Air® SR, Semi Resorbable Reinforcement Parietal Implant; Sterile Neurological Patches: Biomesh™ N3 and N3L, Cranial and Spinal Dura Mater Substitutes; Sterile Adjustable gastric banding with adhesive mesh support for the implantable port Adhesix® Bioring®.**

**Class I Sterile: "Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions".**

**Sterile Non implantable medical devices for spinal surgery comprising:  
Ligament system for spinal stabilization.**

## **COUSIN BIOTECH s.a.s.**

### **Directive 93/42/EEC**

on medical devices, Annex II (excluding Section 4)

### **Directive 93/42/EEC**

Dispositifs médicaux, Annexe II (section 4 exclue)

Issue / Version 38

**Implants stériles de renforcement pariétal non résorbables (plaques et plugs abdominaux et plaques et plugs de renforcement de la paroi abdominale); Anneaux gastriques ajustables stériles; Ligaments articulaires non résorbables stériles ; Ligaments élastiques non résorbables stériles; Dispositifs d'ancrage stériles; Dispositifs stériles pour l'espace inter épineux (avec appui épineux ou avec appui laminaire); Prothèses intervertébrales stériles; Implants urogénitaux stériles (Bandelettes de support sous urétrales et Implants pour le traitement du prolapsus); Prothèses d'essai non-stériles pour les chirurgies rachidienne et viscérale; Système ligamentaire stérile pour stabilisation rachidienne; Dispositifs rachidiens stériles de stabilisation postérieure dynamique.**

**Adhesix® Implants de renforcement pariétal adhésifs stériles; Plaques, Plugs et Films semi résorbables stériles: 4DMESH®, 4DDOME®, 4D VENTRAL® and Biomes® CA.B.S.'Air SR®, Implant de renforcement pariétal semi résorbable; Patchs neurologiques stériles Biomes® N3 et N3L, Substituts de la dure mère crânienne et spinale; Anneau gastrique ajustable stérile avec système de fixation adhésif de la chambre implantable Adhesix® Bioring®.**

**Classe I stérile: « Aspects stérilité uniquement – Restreint aux seuls aspects de la fabrication visant à garantir et maintenir la stérilité ».**

**Dispositifs médicaux non implantables stériles pour la chirurgie rachidienne comprenant: Système ligamentaire pour stabilisation rachidienne.**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Lorsque le périmètre ci-dessus inclus un Dispositif Médical de classe III, un certificat d'examen CE de Conception (ECDE) suivant l'annexe II (section 4) valide, en addition du présent certificat est une exigence obligatoire pour la mise sur le marché de chaque dispositif

Additional facilities/Sites additionnels

**Allée des Roses, 59117 Wervicq-Sud, France**



# EC CERTIFICATE

## Locamed

Enterprise Centre Unit 3 and 4  
Farnham GU10 5EH UNITED KINGDOM

## Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

**Supply of Disposable Laparoscopic Medical Devices, Microsurgery Medical Devices and Accessories**

Device Classifications:

Class IIa  
Class IIb

Device Descriptions and Model Type:

**Please refer to Attachments: 1**

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 5 attachments listing model numbers.

File Number A18039  
Certificate Number 812.180129

Cycle Start Date January 29, 2018  
Effective Date January 29, 2018  
Expiry Date January 28, 2023

Authorised by

Paul Daysh

Medical Notified Body Operations Manager  
For and on Behalf of UL International (UK) Ltd

Notified Body

**0843**

MDD A2 S3 FQ VM  
00-NB-F0051 Issue: 13.0

UL International (UK) Limited  
Wonersh House, The Guildway, Old Portsmouth Road,  
Guildford, Surrey, GU3 1LR, United Kingdom



# EC CERTIFICATE

## Locamed

Enterprise Centre Unit 3 and 4  
Farnham GU10 5EH UNITED KINGDOM

### Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Classification
Laparoscopic Instruments	LM8 Series	Class IIa/IIb
	APPLIER Series	Class IIb
	LM7 Series	Class IIb
	LM3 Series	Class IIa
	LM2 Series	Class IIb
	LM 9 Series	Class IIb
Supplementary Products	LM1 Series	Class IIa
	LM4 Series	Class IIa
Trocars	LM5 Series	Class IIa
Wound Retractors	LMQ Series	Class IIa
Ligating Clips	Clips Cartridge Series	Class IIb

File Number A18039  
Certificate Number 812.180129

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UL International (UK) Limited  
Wonersh House, The Guildway, Old Portsmouth Road,  
Guildford, Surrey, GU3 1LR, United Kingdom

## **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**

**PETERS SURGICAL  
42 rue Benoît Frachon  
93013 BOBIGNY CEDEX FRANCE**

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

**Instruments chirurgicaux endoscopiques à usage unique : ciseaux, pinces, crochets, aiguilles de pneumopéritoine, trocars, systèmes de rétraction laparoscopique, manipulateurs utérin et rectal et câbles de connexion électrique pour des applications en chirurgie et électrochirurgie digestive, gynécologique et urologique.**

*Disposable surgical endoscopic instruments: scissors, forceps, hooks, pneumoperitoneum needles, trocars, laparoscopic retraction systems, uterine and rectal manipulators and electrical connection cables for the area of surgical and electrosurgical applications for digestive, gynaecological and urological surgeries.*

Voir détails sur addendum / See attachment for additional information

**Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P175460-1, 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.**

*LNE/G-MED certifies that, on the basis of the results contained in the file referenced P175460-1, 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 30th, 2018 (included)**

**Valable jusqu'au / Expiry date : April 29th, 2021 (included)**



**On behalf of the G-MED Certification Director  
Béatrice LYS  
G-MED Certification Technical Director**

## Identification des dispositifs / Identification of devices

**Instruments chirurgicaux endoscopiques à usage unique : ciseaux, pinces, crochets, aiguilles de pneumopéritoine, trocars, systèmes de rétraction laparoscopique, manipulateurs utérin et rectal et câbles de connexion électrique pour des applications en chirurgie et électrochirurgie digestive, gynécologique et urologique.**

*Disposable surgical endoscopic instruments: scissors, forceps, hooks, pneumoperitoneum needles, trocars, laparoscopic retraction system, uterine and rectal manipulators and electrical connection cables for the area of surgical and electrosurgical applications for digestives, gynaecological and urological surgeries.*

REFERENCE	DESIGNATION	CLASSE
C5 470	Ciseaux monopolaires <i>Monopolar scissors</i>	IIb
IC5 330	Ciseaux monopolaires <i>Monopolar scissors</i>	IIb
IK5 330	Ciseaux monopolaires <i>Monopolar scissors</i>	IIb
A5 330	Pince atraumatique monopolaire <i>Monopolar atraumatic grasping forceps</i>	IIb
F5 330	Pince atraumatique monopolaire <i>Monopolar atraumatic grasping forceps</i>	IIb
G5 330	Pince monopolaire <i>Monopolar grasping forceps</i>	IIb
MD5 330	Dissecteur monopolaire <i>Monopolar dissector</i>	IIb
BP5330	Pince bipolaire "Kali®" <i>"Kali®" Bipolar forceps</i>	IIb
H5330	Crochet monopolaire <i>Monopolar hook</i>	IIb
H5330L	Crochet monopolaire <i>Monopolar hook</i>	IIb
ECS5 330	Pince atraumatique <i>Atraumatic grasping forceps</i>	IIa
5053	Trocart <i>Trocar</i>	IIa
5068	Trocart <i>Trocar</i>	IIa

LNE/G-MED

0459



On behalf of the Certification Director  
Béatrice LYS

G-MED Certification Technical Director

720 DM 0701-31 rev 5 du 28/07/2015

ADD

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial

LNE/G-MED • Organisme notifié n° 0459

1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

5100	Trocart <i>Trocar</i>	Ila
11060	Trocart <i>Trocar</i>	Ila
12060	Trocart <i>Trocar</i>	Ila
11100	Trocart <i>Trocar</i>	Ila
12100	Trocart <i>Trocar</i>	Ila
5053H	Trocart à pointe mousse <i>Blunt tip trocar</i>	Ila
12100H	Trocart à pointe mousse <i>Blunt tip trocar</i>	Ila
11100S	Trocart à pointe bouclier <i>Shielded tip trocar</i>	Ila
CAUT60	Manipulateur utérin <i>Uterine manipulator</i>	Ila
MAUT60	Manipulateur utérin chirurgical <i>Surgical uterine manipulator</i>	Ila
RCC320	Canule rectale <i>Rectal cannula</i>	Ila
AIG2 120	Aiguille de pneumopéritoine <i>Pneumoperitoneum needle</i>	Ila
AIG2 150	Aiguille de pneumopéritoine <i>Pneumoperitoneum needle</i>	Ila
AW16 280	Ecarteur suspenseur T'lift® <i>Retraction system T'lift®</i>	Ila

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

*This certificate covers the following sites and activities:*

- ☛ **42 rue Benoît Frachon - 93013 BOBIGNY Cedex – France**  
Siège social – Responsable de la mise sur le marché - Fabrication - Contrôle final - Commercialisation  
*Headquarters – Legal manufacturer - Manufacturing - Final control – Sales*
- ☛ **Bioparc - 03270 HAUTERIVE - France**  
Conception – Fabrication – Contrôle final  
*Design – Manufacturing – Final control*

**2 sites / 2 sites**

**LNE/G-MED 0459**



**On behalf of the Certification Director**  
**Béatrice LYS**  
**G-MED Certification Technical Director**

720 DM 0701-31 rev 5 du 28/07/2015

ADD

**Laboratoire national de métrologie et d'essais** • Établissement public à caractère industriel et commercial

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1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr



**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60118281 0001

**Report No.:** 17025753 007

**Manufacturer:** Guangzhou T.K Medical  
Instrument Co., Ltd.  
A601, Guangzhou International  
Business Incubator  
Guangzhou Science Park  
510663 Guangzhou, Guangdong  
China

**Products:** Medical Devices  
  
(see attachment for products included)

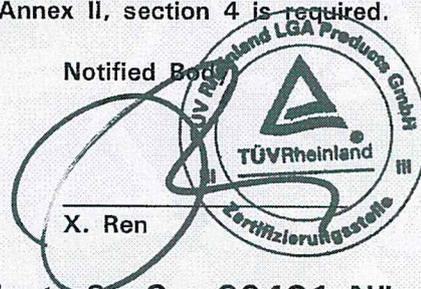
Replaces Approval, Registration No.: HD 60111303 0001

**Expiry Date:** 2022-08-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2017-08-10

**Date:** 2017-08-03



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60118281 0001  
**Report No.:** 17025753 007

**Manufacturer:** Guangzhou T.K Medical  
Instrument Co., Ltd.  
A601, Guangzhou International  
Business Incubator  
Guangzhou Science Park  
510663 Guangzhou, Guangdong  
China

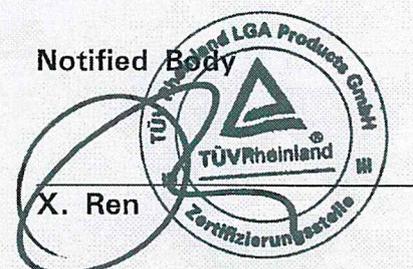
**Products:**

- Retriever Bags
- Trocar Kits
- Trocars
- Veress Needles
- Wound Protectors/Retractors
- OSA Appliance
- Disposable Traction Belts
- Disposable Tracers
- Surgical Drapes

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

- Disposable Drainage Catheter Fixators

**Date:** 2017-08-03





EC Certificate Full Quality Assurance System: Certificate IN15/93310

The management system of

# Veol Medical Technologies Pvt. Ltd.

Plot - A 747, Near Pavan Bus Stop, Pawane MIDC, TTC Industrial Estate,  
Koparkhairane, Navi Mumbai, Maharashtra - 400705, India

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**Morsafe Tissue Morcellation Bag (Sterile) for containment and retrieval  
of morcellated tissue in gynaecological laparoscopic procedures  
using a power morcellator.**

**Tissue Morcellation System (Versator) comprising of Drive unit, Rotor  
cable & Sterile hand piece for gynaecologic, urologic and general  
surgical endoscopic use in a hospital environment and ambulatory  
surgery centres.**

Where the above scope includes class III medical device(s), a valid EC Design Examination  
Certificate according to Annex II (Section 4) is a mandatory requirement for each device in  
addition to this certificate to place that device on the market.

This certificate is valid from 18 June 2018 until 18 June 2023  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 30 December 2020  
Issue 2. Certified since 18 June 2015

Certification is based on reports numbered IN/MJM 235610

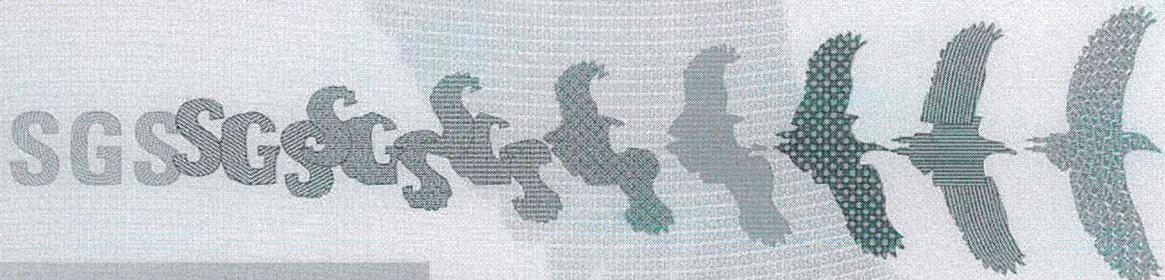
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**SGS United Kingdom Ltd, Notified Body 0120**

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