



Le progrès, une passion à partager

Certification
Médical-Santé



CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 8343 Révision 4

Le LNE certifie que le système de management de la qualité développé par
LNE certifies that the quality management system developed by

LINA MEDICAL APS
Formervangen 5,
2600 GLOSTRUP DENMARK

pour les activités
for the activities

Conception, fabrication et distribution d'instruments et accessoires pour l'électrochirurgie - l'évacuation de fumée en bloc opératoire - la laparoscopie - la gynécologie - l'obstétrique - la chirurgie générale - l'orthopédie et la fixation et de dispositifs de traitement de la plaie.
Conditionnement en sous-traitance.

Design, manufacture and distribution of instruments and accessories for electrosurgery - smoke evacuation from theatre - laparoscopy - gynaecology - obstetrics - general surgery - orthopaedics and fixation & wound-care products.

Subcontract packaging of procedure packs.

réalisées sur le(s) site(s) de
performed on the location(s) of

LINA MEDICAL APS
Formervangen 5, 2600 Glostrup DENMARK
LINA MEDICAL Polska sp. z.o.o.
Sady, Ul. Rolna 8, 62-080 Tarnowo Podgorne POLAND

est conforme aux exigences des normes Internationales
complies with the requirements of the international standards

ISO 9001 : 2008 - NF EN ISO 13485 : 2004

Début de validité / Effective date : May 18th, 2012 (Included)

Valable jusqu'au / Expiry date : May 17th, 2015 (included)

Etabli le / Issued on : May 3rd, 2012

cofrac



CERTIFICATION
D'ENTREPRISES
& DE PRODUIS

N° 4-0038

Portée disponible
sur www.cofrac.fr

LNE N° 8343-4

Ce certificat est délivré selon les règles de certification G-MED
LNE/G-MED Organisme notifié pour les Dispositifs Médicaux

/ This certificate is issued according to the rules of G-MED certification
/ LNE/G-MED Notified Body for Medical Devices

Renouvelle le certificat 8343-3



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

ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'Assurance Qualité de la Production (limitée à l'obtention et au maintien de l'état stérile)
Approval of Production Quality Assurance System (related to securing and maintaining sterile conditions)

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant (nom et adresse) / Manufacturer (name and address)

LINA MEDICAL APS
Formervangen 5,
2600 GLOSTRUP DENMARK

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

**Rétracteurs chirurgicaux stériles à usage unique - Accessoires stériles pour l'extraction de fumée
- Dispositifs stériles de fixation des cathéters et de compression - Sets stériles pour le traitement
de la plaie, le changement de cathéter, les soins et l'accouchement - Tube colpotomie stérile**

*Sterile disposable surgical retractors - Sterile accessories for smoke evacuation - Sterile devices for
fixation of catheters and compression - Sterile procedure packs for wound dressing, catheter changing,
exudate absorption, and obstetric delivery - Sterile colpotomy tube*

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé M050408, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced M050408, the quality system -for manufacturing and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex V section 3.

Début de validité / Effective date : May 18th, 2012 (included)

Valable jusqu'au / Expiry date : May 17th, 2015 (included)



VO 04-07-2007

LNE - 8342 rev. 3
Renouvelle le certificat 8342-2



TO WHOM IT MAY CONCERN

Glostrup, 7th January 2013

Copenhagen MedLab

We, LiNA Medical ApS, hereby certify that

Copenhagen MedLab

is a division of LiNA Medical CML ApS and as such a fully integrated part of LiNA Medical both legally and financially.

LiNA Medical mainly manufactures instruments and accessories for laparoscopy as well as for open surgery and markets these products through a net of distributors specialized in the surgical field.

Products aimed at other segments within the healthcare sector are still manufactured by LiNA Medical, but marketed under the name of Copenhagen MedLab. In most markets these products are sold through distributors who do not specifically target the surgical field, but various other fields within the health care sector.

This procedure has been chosen in order to avoid confusion about who is selling which products in the market place.

If you have any questions relating to the above then please do not hesitate to contact us. We shall be at your service at any time.

Yours sincerely,
LiNA Medical ApS


Janni Strassmann
Financial Controller



DECLARATION OF CONFORMITY

with the
Medical Device Directive

We,

LiNA Medical ApS
Formervangen 5
2600 Glostrup
Denmark

declare that the catalogue number(s):

REF: 8055-01n, 8065n, 8065-Cn, 8055-01n-US

are in conformity with the European Medical Device Directive 93/42/EEC amended by 2007/47/EC in effect as of 21st of March 2010 and pertinent national statutory order

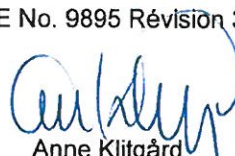
Lina Medical product family: Dia-Stop
Annex V
MDD Classification: Is
MDD Rule: 4

In addition, the Quality System is certified and in compliance with the requirements of ISO13485:2003
LiNA Medical ApS applies the obligations of its Quality System for this product

Notified Body: LNE # 0459

EC certificate ID: LNE No. 9895 Révision 3

Glostrup 2012.10.02


Anne Klitgård
QA/RA Manager