ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

Digitally signed by Bolea Petru
Date: 2022.11.11 11:34:23 EET
Reason: MoldSign Signature
Location: Moldova

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate.
The certificate is subject to terms and conditions overleaf.
Any significant changes in design or manufacture may render this certificate invalid.

Certificate Number: 301011860AD

This certificate is issued to replace certificate nr 301011860TN due to the addition of new products.

Manufacturer:	**LUX - SUTURES S.A.**
Facility:	**22, GRUUSS - STROOSS 9991 WEISWAMPACH, LUXEMBOURG.**
Products:	**1. STERILE NON ABSORBABLE SURGICAL SUTURES.** **2. STERILE ABSORBABLE SURGICAL SUTURES.** **3. STERILE SURGICAL BLADES.** **4. STERILE DISPOSABLE SKIN STAPLER.**
Brand names:	***As in annex***
Devices Classification:	**1. IIb, 2. III., 3. IIa, 4. IIa.**
First issue date:	**01/03/2021**
Current issue date:	**25/05/2021**
Valid until:	**24/05/2024**
Audit report:	**200011860**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.
National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.

ΣΜΥΡΝΗΣ 13-15 | 165 62 ΓΛΥΦΑΔΑ • 13-15 SMYRNIS | 165 62 GLYFADA - GREECE
T: +30 2132026200 | F: +30 210 9615464 | e-mail: info@ekapty.gr | www.ekapty.gr

ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

ANNEX No. 301011860AD CERTIFICATE.

MEDICAL DEVICES	BRAND NAMES
• ***Classification IIb*** 1. **STERILE NON ABSORBABLE SURGICAL SUTURES.**	• **LUXAMID & SUPRAMID** • **LUXPET** • **SILK** • **STEEL** • **LUXYLENE**
• ***Classification III*** 2. **STERILE ABSORBABLE SURGICAL SUTURES.**	• **LUXCRYL 910** • **LUXCRYL PGA** • **LUXCRYL PDO** • **LUXCRYL MONOFAST** • **LUXCRYL PGA RAPID**

TERMS & CONDITIONS

1. For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. The certificate is valid only for the products and the facilities mentioned.
5. Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

ΣΜΥΡΝΗΣ 13-15 | 165 62 ΓΛΥΦΑΔΑ • 13-15 SMYRNIS | 165 62 GLYFADA - GREECE
T: +30 2132026200 | F: +30 210 9615464 | e-mail: info@ekapty.gr | www.ekapty.gr