



ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

CERTIFICATE
EN ISO 13485:2016

We hereby certify that the under mentioned organization has established and maintains for the listed activities a quality management system that complies with the requirements of the standard.
Validity of the certificate is based upon the successful completion of surveillance audits.

Certificate Number: 302011860M

This certificate is issued to replace certificate nr 302011860 due to the expansion of activity.

Organization: **LUX - SUTURES S.A.**

Address: **22, GRUUSS - STROOSS 9991 WEISWAMPACH, LUXEMBOURG.**

Activities: **MANUFACTURE AND DISTRIBUTION OF STERILE MEDICAL DEVICES INCLUDING ABSORBABLE AND NON ABSORBABLE SURGICAL SUTURES, SURGICAL BLADES AND DISPOSABLE SKIN STAPLER.**

First issue date: **01/03/2021**


Current issue date: **09/06/2021**

Valid until: **01/03/2024**

Audit report: **200011860**



Πιστοποίηση ΣΔ
Αρ. Πιστ.: 58-5


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

ΣΜΥΡΝΗΣ 13-15 | 165 62 ΓΛΥΦΑΔΑ • 13-15 SMYRNIIS | 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.

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.



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
<ul style="list-style-type: none">• <i>Classification IIb</i> <p>1. STERILE NON ABSORBABLE SURGICAL SUTURES.</p>	<ul style="list-style-type: none">• LUXAMID & SUPRAMID• LUXPET• SILK• STEEL• LUXYLENE
<ul style="list-style-type: none">• <i>Classification III</i> <p>2. STERILE ABSORBABLE SURGICAL SUTURES.</p>	<ul style="list-style-type: none">• 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

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.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

10 May 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

SURGICAL BLADES

Sterile surgical blades
GMDN code: 37445

SURGICAL BLADES STERILE	REF	UNIT
SURGICAL BLADES STERILES N° 10	LUSB10	100 Pc.
SURGICAL BLADES STERILES N° 11	LUSB11	100 Pc.
SURGICAL BLADES STERILES N° 12	LUSB12	100 Pc.
SURGICAL BLADES STERILES N° 12d	LUSB12D	100Pc.
SURGICAL BLADES STERILES N° 15	LUSB15	100 Pc.
SURGICAL BLADES STERILES N° 15c	LUSB15C	100 Pc.
SURGICAL BLADES STERILES N° 18	LUSB18	100 Pc.
SURGICAL BLADES STERILES N° 20	LUSB20	100 Pc.
SURGICAL BLADES STERILES N° 21	LUSB21	100 Pc.
SURGICAL BLADES STERILES N° 22	LUSB22	100 Pc.
SURGICAL BLADES STERILES N° 23	LUSB23	100 Pc.
SURGICAL BLADES STERILES N° 24	LUSB24	100 Pc.
SURGICAL BLADES STERILES N° 25	LUSB25	100 Pc.
STITCH CUTTER	LUSC	100 Pc.
SURGICAL BLADES STERILES N° 10	LUSD10	10 Pc.
SURGICAL BLADES STERILES N° 11	LUSD11	10 Pc.
SURGICAL BLADES STERILES N° 12	LUSD12	10 Pc.
SURGICAL BLADES STERILES N° 15	LUSD15	10 Pc.
SURGICAL BLADES STERILES N° 20	LUSD20	10 Pc.
SURGICAL BLADES STERILES N° 21	LUSD21	10 Pc.
SURGICAL BLADES STERILES N° 22	LUSD22	10 Pc.
SURGICAL BLADES STERILES N° 23	LUSD23	10 Pc.
SURGICAL BLADES STERILES N° 24	LUSD24	10 Pc.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class IIa (Annex IX Rule 6). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", with a horizontal line underneath.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

10 May 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach - LUXEMBOURG

We herewith declare under our sole responsibility that the product:

DISPOSABLE SKIN STAPLER

Reference: LUSS / Description: LUXSUTURES SKIN STAPLER 35 W

Sterile, single patient use medical device containing stainless steel skin staples for skin closure

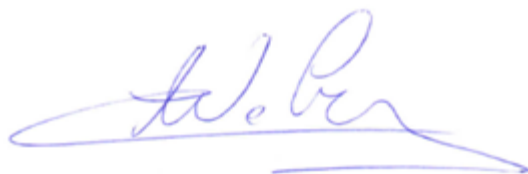
GMDN code: 46332

is a Medical Device and has been classified as Class IIa (Annex IX Rule 7). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager



LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

LUXAMID

**Polyamide - Nylon - sterile non-absorbable suture in foil packs
In atraumatic needle and without needle
GMDN code: 38000**

Needle Description	
Characteristics	Description
Needle Types & Codes	Taper point 1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting 1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass 3/8 circle (DS)
	Tapercut 1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting 3/8 circle (NS), 1/2 circle (NH)
	Spatula 1/2, 3/8, 1/4 circle or straight
	Blunt point 1/2 circle (HRB), 3/8 circle (DRB)
	Micro needle – taper point 3/8 circle
	Without needle n/a
Number of Needles	1 or 2
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight
Needle Length Range	3 mm to 100 mm
Suture Thread Characteristics	
Suture Color	Black or blue
Suture Gauge sizes (USP)	2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0, 8/0, 9/0, 10/0, 11/0
Suture Length Range	10 cm - 250 cm
Quantity per Pouch	1-17
Presentation	Sterile sutures in foil packs

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class IIb (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", written over a horizontal line.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

LUXCRYL MONOFAST

**Polyglecaprone 25 - Sterile Synthetic Absorbable Suture
In atraumatic needle and without needle
GMDN code: 45814**

Needle Description	
Characteristics	Description
Needle Types & Codes	Taper point 1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting 1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass 3/8 circle (DS)
	Tapercut 1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting 3/8 circle (NS), 1/2 circle (NH)
	Spatula 1/2, 3/8 or 1/4 circle
	Blunt point 1/2 circle (HRB), 3/8 circle (DRB)
	Without needle n/a
Number of Needles	1 or 2
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight
Needle Length Range	6 mm to 100 mm
Suture Thread Characteristics	
Type	Monofilament
Suture Color	Undyed or Violet
Suture Gauge sizes (USP)	2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0
Suture Length Range	20 cm - 250 cm
Quantity per Pouch	1-17
Presentation	Sutures in foil packs

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

Has been classified as Class III (Annex IX Rule 8) and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", written over a horizontal line.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

LUXCRYL PDO

Sterile Synthetic Polydioxanone (PDO) Absorbable Suture
In atraumatic needle and without needle
GMDN code: 16584

Needle Description		
Characteristics	Description	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass	3/8 circle (DS)
	Tapercut	1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting	3/8 circle (NS), 1/2 circle (NH)
	Spatula	1/2, 3/8 or 1/4 circle
	Blunt point	1/2 circle (HRB), 3/8 circle (DRB)
	Without needle	n/a
Number of Needles	1 or 2	
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight	
Needle Length Range	6 mm to 110 mm	
Suture Thread Characteristics		
Suture Color	Violet	
Suture Gauze sizes (USP)	4, 3, 2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0	
Suture Length Range	20 cm - 150 cm	
Quantity per Pouch	1-8	
Presentation	Sutures in foil packs	

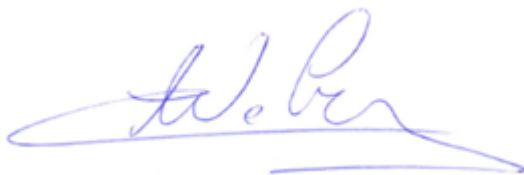
LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class III (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", written over a horizontal line.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

**Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG**

We herewith declare under our sole responsibility that the product:

LUXPET

**Polyester - sterile non-absorbable suture in foil packs
In atraumatic needle and without needle
GMDN code: 13906**

Needle Description		
Characteristics	Description	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass	3/8 circle (DS)
	Tapercut	1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting	3/8 circle (NS), 1/2 circle (NH)
	Spatula	1/2, 3/8 or 1/4 circle
	Blunt point	1/2 circle (HRB), 3/8 circle (DRB)
	Without needle	n/a
Number of Needles	1 or 2	
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight	
Needle Length Range	6 mm to 100 mm	
Suture Thread Characteristics		
Suture Color	Green or White	
Suture Gauze sizes (USP)	5, 3&4, 2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0	
Suture Length Range	20 cm - 250 cm	
Quantity per Pouch	1-17	
Presentation	Sterile sutures in foil packs	

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class IIb (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", written over a horizontal line.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

LUXCRYL PGA

Sterile Polyglycolic Acid Absorbable Surgical Suture
In atraumatic needle and without needle
GMDN code: 13908

Needle Description		
Characteristics	Description	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass	3/8 circle (DS)
	Tapercut	1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting	3/8 circle (NS), 1/2 circle (NH)
	Spatula	1/2, 3/8 or 1/4 circle
	Blunt point	1/2 circle (HRB), 3/8 circle (DRB)
	Without needle	n/a
Number of Needles	1 or 2	
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight	
Needle Length Range	6 mm to 110 mm	
Suture Thread Characteristics		
Suture Color	Violet or Undyed	
Suture Gauze sizes (USP)	5, 4, 3, 2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0, 8/0, 9/0, 10/0, 11/0	
Suture Length Range	10 cm - 250 cm	
Quantity per Pouch	1-17	
Presentation	Sutures in foil packs	

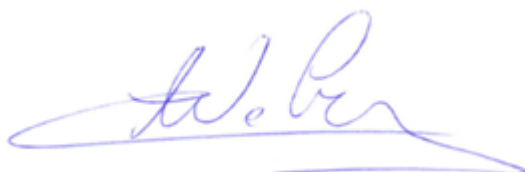
LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class III (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber".

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

LUXCRYL PGA RAPID

**Sterile Polyglycolic Acid Absorbable Surgical Suture
In atraumatic needle(s) and without needle
GMDN code: 13908**

Needle Description		
Characteristics	Description	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass	3/8 circle (DS)
	Tapercut	1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting	3/8 circle (NS), 1/2 circle (NH)
	Spatula	1/2, 3/8 or 1/4 circle
	Blunt point	1/2 circle (HRB), 3/8 circle (DRB)
	Without needle	n/a
Number of Needles	1 or 2	
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight	
Needle Length Range	6 mm to 100 mm	
Suture Thread Characteristics		
Suture Color	Undyed	
Suture Gauze sizes (USP)	5, 4, 3, 2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0, 8/0	
Suture Length Range	20 cm - 150 cm	
Quantity per Pouch	1-17	
Presentation	Sutures in foil packs	

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

Has been classified as Class III (Annex IX Rule 8) and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber".

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

**Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG**

We herewith declare under our sole responsibility that the product:

LUXCRYL 910

**Polyglactine 910 - Sterile Synthetic Absorbable Suture
In atraumatic needle and without needle
GMDN code: 17471**

Needle Description		
Characteristics	Description	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR, MDR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass	3/8 circle (DS)
	Tapercut	1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting	3/8 circle (NS), 1/2 circle (NH)
	Spatula	1/2, 3/8 or 1/4 circle
	Blunt point	1/2 circle (HRB), 3/8 circle (DRB)
	Without needle	n/a
Number of Needles	1 or 2	
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight	
Needle Length Range	6 mm to 110 mm	
Suture Thread Characteristics		
Suture Color	Violet or Undyed	
Suture Gauze sizes (USP)	2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0, 8/0	
Suture Length Range	20 cm - 250 cm	
Quantity per Pouch	1-17	
Presentation	Sutures in foil packs	

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class III (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager



LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

LUXYLENE

**Polypropylene - sterile non-absorbable suture in foil packs
In atraumatic needle and without needle
GMDN code: 13909**

Needle Description		
Characteristics	Description	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass	3/8 circle (DS)
	Tapercut	1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting	3/8 circle (NS), 1/2 circle (NH)
	Spatula	1/2, 3/8, 1/4 circle or straight
	Blunt point	1/2 circle (HRB), 3/8 circle (DRB)
	Soft cutting point - coronar	3/8 circle
	Micro needle – taper point	3/8 circle
	Without needle	n/a
Number of Needles	1 or 2	
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight	
Needle Length Range	5 mm to 100 mm	
Suture Thread Characteristics		
Suture Color	Blue	
Suture Gauze sizes (USP)	2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0, 8/0, 9/0, 10/0	
Suture Length Range	15 cm - 250 cm	
Quantity per Pouch	1-17	
Presentation	Sterile sutures in foil packs	

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class IIb (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", with a horizontal line underneath.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

**Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG**

We herewith declare under our sole responsibility that the product:

SUPRAMID

**Polyamide - sterile non-absorbable suture in foil packs
In atraumatic needle and without needle
GMDN code: 38000**

Needle Description	
Characteristics	Description
Needle Types & Codes	Taper point 1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting 1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass 3/8 circle (DS)
	Tapercut 1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting 3/8 circle (NS), 1/2 circle (NH)
	Spatula 1/2, 3/8 or 1/4 circle
	Blunt point 1/2 circle (HRB), 3/8 circle (DRB)
	Without needle n/a
Number of Needles	1 or 2
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight
Needle Length Range	6 mm to 100 mm
Suture Thread Characteristics	
Suture Color	Black
Suture Gauge sizes (USP)	2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0
Suture Length Range	20 cm - 250 cm
Quantity per Pouch	1-17
Presentation	Sterile sutures in foil packs

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class IIb (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", written over a horizontal line.

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

SILK

Silk - sterile non-absorbable suture in foil packs
In atraumatic needle and without needle
GMDN code: 13910

Needle Description	
Characteristics	Description
Needle Types & Codes	Taper point 1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting 1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass 3/8 circle (DS)
	Tapercut 1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting 3/8 circle (NS), 1/2 circle (NH)
	Spatula 1/2, 3/8 or 1/4 circle
	Blunt point 1/2 circle (HRB), 3/8 circle (DRB)
	Without needle n/a
Number of Needles	1 or 2
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight
Needle Length Range	6 mm to 100 mm
Suture Thread Characteristics	
Suture Color	Black or blue
Suture Gauze sizes (USP)	5, 4, 3, 2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0, 8/0, 9/0, 10/0
Suture Length Range	20 cm - 250 cm
Quantity per Pouch	1-17
Presentation	Sterile sutures in foil packs

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a medical device and has been classified as Class IIb (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber".

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

01 March 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

STEEL

Stainless Steel - sterile non-absorbable suture in foil packs
In atraumatic needle and without needle
GMDN code: 15971

Needle Description		
Characteristics	Description	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Tapercut	1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting	1/2 circle (NH), 3/8 circle (NS)
	Without needle	n/a
Number of Needles	1	
Needle Angle Range	3/8, 1/2, J, Straight	
Needle Length Range	12 mm to 120 mm	
Suture Thread Characteristics		
Suture Color	Metal	
Suture Gauze sizes (USP)	7, 6, 5, 4, 3, 2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0	
Suture Length Range	20 cm - 150 cm	
Quantity per Pouch	1-4	
Presentation	Sterile sutures in foil packs	

LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

is a Medical Device and has been classified as Class IIb (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", written over a horizontal line.