



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

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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**

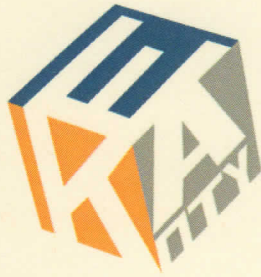
Valid until: **24/05/2024**

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

ANNEX No. 301011860AD CERTIFICATE.

| MEDICAL DEVICES  | BRAND NAMES  |
|--|--|
| <ul style="list-style-type: none"><li>• <i>Classification IIb</i></li></ul> <p>1. STERILE NON ABSORBABLE SURGICAL SUTURES.</p> | <ul style="list-style-type: none"><li>• LUXAMID &amp; SUPRAMID</li><li>• LUXPET</li><li>• SILK</li><li>• STEEL</li><li>• LUXYLENE</li></ul>                      |
| <ul style="list-style-type: none"><li>• <i>Classification III</i></li></ul> <p>2. STERILE ABSORBABLE SURGICAL SUTURES.</p>     | <ul style="list-style-type: none"><li>• LUXCRYL 910</li><li>• LUXCRYL PGA</li><li>• LUXCRYL PDO</li><li>• LUXCRYL MONOFAST</li><li>• LUXCRYL PGA RAPID</li></ul> |

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.

  
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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**

| <b>SURGICAL BLADES STERILE</b>  | <b>REF</b> | <b>UNIT</b> |
|---------------------------------|------------|-------------|
| 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.      |

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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".

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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

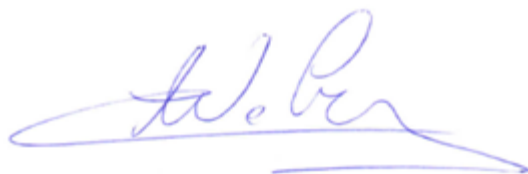
**GMDN code: 46332**

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



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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                               |   |

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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

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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            |   |

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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

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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                       |   |

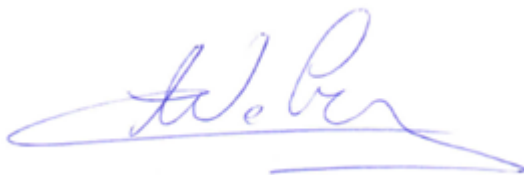
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is a medical device and has been classified as Class III (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

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

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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                 |   |


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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.

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Name and function of the responsible person:

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QA & RA Manager

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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  |   |

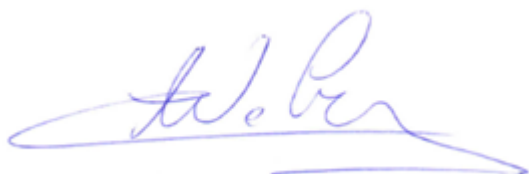
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is a medical device and has been classified as Class III (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

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Name and function of the responsible person:

Nico WEBER  
QA & RA Manager

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01 March 2021

## DECLARATION OF CONFORMITY

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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                               |   |

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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

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Name and function of the responsible person:

Nico WEBER  
QA & RA Manager

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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                      |  |

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Name and function of the responsible person:

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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                         |   |

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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<br>1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR),<br>J needle (JR), Straight (GR) |
|                               | Reverse cutting<br>1/2 circle (HS), 3/8 circle (DS), Straight (GS)                                |
|                               | Reverse cutting Easy Pass<br>3/8 circle (DS)  |
|                               | Tapercut<br>1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)                                    |
|                               | Cutting<br>3/8 circle (NS), 1/2 circle (NH)   |
|                               | Spatula<br>1/2, 3/8 or 1/4 circle   |
|                               | Blunt point<br>1/2 circle (HRB), 3/8 circle (DRB)   |
|                               | Without needle<br>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   |

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**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<br>1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR),<br>J needle (JR), Straight (GR) |
|                               | Reverse cutting<br>1/2 circle (HS), 3/8 circle (DS), Straight (GS)                                |
|                               | Reverse cutting Easy Pass<br>3/8 circle (DS)  |
|                               | Tapercut<br>1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)                                    |
|                               | Cutting<br>3/8 circle (NS), 1/2 circle (NH)   |
|                               | Spatula<br>1/2, 3/8 or 1/4 circle   |
|                               | Blunt point<br>1/2 circle (HRB), 3/8 circle (DRB)   |
|                               | Without needle<br>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   |

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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 Gauge 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                   |  |

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