

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

Weiswampach, 19/09/2019

### **DECLARATION OF CONFORMITY**

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

hereby declares that the product:

**LUXYLENE**

**Polypropylene - sterile non-absorbable suture in foil packs**  
**In atraumatic needle and without needle**

| 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 Lenght 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 Lenght Range           | 15 cm - 250 cm  |   |
| Quanityty 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 Notified Body,

- **LRQA (LLOYD'S REGISTER QUALITY ASSURANCE LIMITED)**
- 1 Trinity Park Bickenhill Lane, Birmingham B37 7ES
- United Kingdom
- **Notified Body identification number : 0088**
- **CE No° LRQ00001135/B**

Name and function of the responsible person:

Nico WEBER  
QA & RA Manager

