Weiswampach, 01 October 2019

DECLARATION OF CONFORMITY

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

hereby declares that the product:

LUXCRYL 910

Polyglactine 910 - Sterile Synthetic Absorbable Suture
In atraumatic needle and without needle

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 Lenght 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 Lenght Range	20 cm - 250 cm	
Quanitity per Pouch	1-17	
Presentation	Sutures in foil packs	

LUXSUTURES A.G.
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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 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