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

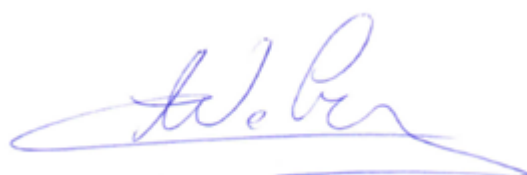| Needle Description		
Characteristics	**Description**	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass	3/8 circle (DS)
	Tapercut	1/2 circle (HRT), 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 Lenght 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 Lenght Range	20 cm - 150 cm	
Quantity per Pouch	1-8	
Presentation	Sutures in foil packs	

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