

LUX-SUTURES S.A.
22, Gruuss-Strooss
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LUXEMBOURG
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Tel.: 00352-2030-1449

25 May 2021

EC-DECLARATION OF CONFORMITY

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

We herewith declare under our sole responsibility that the following medical devices conform to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

Product Name	Description	Class - Annex IX	GMDN Code
LUXCRYL 910	Sterile Synthetic Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-PL product list	Class III	17471
LUXCRYL PGA	Sterile Synthetic Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-PG product list	Class III	13908
LUXCRYL PDO	Sterile Synthetic Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-PD product list	Class III	16584
LUXCRYL PGA RAPID	Sterile Synthetic Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-PGR product list	Class III	13908
LUXCRYL MONOFAST	Sterile Synthetic Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-PC product list	Class III	45814
LUXAMID	Sterile Non - Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-NY product list	Class IIb	38000
LUXYLENE	Sterile Non - Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-PP product list	Class IIb	13909

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SUPRAMID	Sterile Non - Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-SB product list	Class IIb	38000
SILK	Sterile Non - Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-SI product list	Class IIb	13910
LUXPET	Sterile Non - Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-PE product list	Class IIb	13906
STEEL	Sterile Non - Absorbable Surgical Suture In atraumatic needle(s) and without needle References: F-E-09-C-ST product list	Class IIb	15971
SURGICAL BLADES	Sterile Surgical Blades References: F-E-09-C-LUSB product list	Class IIa	37445
SKIN STAPLER	Sterile Disposable Skin Stapler References: F-E-09-C-LUSS product list	Class IIa	46332

The afore mentioned products are 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.

EC Certificate No: 301011860AD

Name and function of the responsible person:

Nico WEBER
QA & RA Manager


