

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

SURGICAL BLADES STERILE	REF	UNIT
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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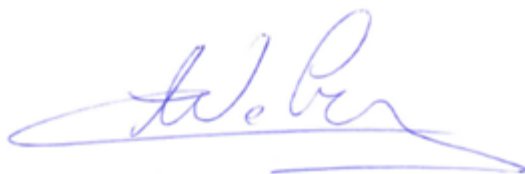
is a medical device and has been classified as Class IIa (Annex IX Rule 6). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

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.

EC Certificate No: 301011860AD

Name and function of the responsible person:

Nico WEBER
QA & RA Manager



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Manufacturer: LUX-SUTURES S.A.
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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

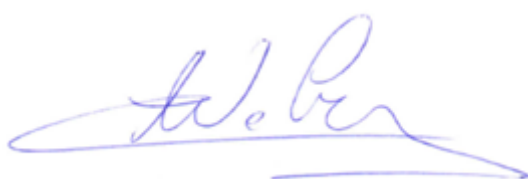
is a Medical Device and has been classified as Class IIa (Annex IX Rule 7). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

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.

EC Certificate No: 301011860AD

Name and function of the responsible person:

Nico WEBER
QA & RA Manager


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Luxembourg

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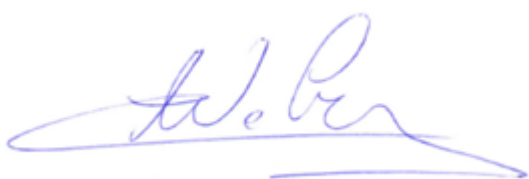
is a medical device and has been classified as Class IIb (Annex IX Rule 8). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

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EC Certificate No: 301011860AD

Name and function of the responsible person:

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QA & RA Manager



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Manufacturer: **LUX-SUTURES S.A.**
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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 Lenght Range	6 mm to 100 mm	
Suture Thread Characteristics		
Type	Monofilament	
Suture Color	Undyed or Violet	
Suture Gauze sizes (USP)	2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0	
Suture Lenght Range	20 cm - 250 cm	
Quanityty per Pouch	1-17	
Presentation	Sutures in foil packs	

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EC Certificate No:	301011860AD
Design Examination Certificate No. (Annex II section 4):	301011860TN_DE4

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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Manufacturer: **LUX-SUTURES S.A.**
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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	

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EC Certificate No: 301011860AD
Design Examination Certificate No. (Annex II section 4): 301011860DE3

Name and function of the responsible person:

Nico WEBER
QA & RA Manager



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Manufacturer: **LUX-SUTURES S.A.**
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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 Lenght 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 Lenght Range	20 cm - 250 cm	
Quanityty per Pouch	1-17	
Presentation	Sterile sutures in foil packs	

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EC Certificate No: 301011860AD

Name and function of the responsible person:

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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 Lenght 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 Lenght Range	10 cm - 250 cm	
Quantity per Pouch	1-17	
Presentation	Sutures in foil packs	

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EC Certificate No: 301011860AD
Design Examination Certificate No. (Annex II section 4): 301011860DE2

Name and function of the responsible person:

Nico WEBER
QA & RA Manager



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DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
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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 Lenght 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 Lenght Range	20 cm - 150 cm	
Quantity per Pouch	1-17	
Presentation	Sutures in foil packs	

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EC Certificate No: 301011860AD
Design Examination Certificate No. (Annex II section 4): 301011860TN_DE5

Name and function of the responsible person:

Nico WEBER
QA & RA Manager



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Manufacturer: **LUX-SUTURES S.A.**
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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 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	
Quaninity per Pouch	1-17	
Presentation	Sutures in foil packs	

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EC Certificate No: 301011860AD
Design Examination Certificate No. (Annex II section 4): 301011860DE1

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 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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Name and function of the responsible person:

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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	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 100 mm	
Suture Thread Characteristics		
Suture Color	Black	
Suture Gauze sizes (USP)	2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0	
Suture Lenght Range	20 cm - 250 cm	
Quanityty per Pouch	1-17	
Presentation	Sterile sutures in foil packs	

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

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.

EC Certificate No: 301011860AD

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:

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	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 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 Lenght Range	20 cm - 250 cm	
Quanityty per Pouch	1-17	
Presentation	Sterile sutures in foil packs	

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EC Certificate No: 301011860AD

Name and function of the responsible person:

Nico WEBER
QA & RA Manager



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DECLARATION OF CONFORMITY

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

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 Lenght Range	12 mm to 120 mm	
Suture Thread Characteristics		
Suture Color	Metal	
Suture Gauze sizes (USP)	7, 6, 5, 4, 3, 2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0	
Suture Lenght Range	20 cm - 150 cm	
Quanityty per Pouch	1-4	
Presentation	Sterile sutures in foil packs	

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EC Certificate No: 301011860AD

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

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