

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** CE 633647  
Issued To: **Internacional Farmacéutica, S.A. de C.V.**  
**Carreteraco No. 44**  
**Colonia Parque San Andrés**  
**Coyoacán**  
**C.P. 04040**  
**Ciudad de México**  
**Mexico**

In respect of:

**Atramat® PGLA90 Polyglactin 910 Poly(glycolide-co-L-lactide) Absorbable Surgical Sutures**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-11-30**

Date: **2020-05-18**

Expiry Date: **2024-05-26**

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Page 1 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.  
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# EC Design-Examination Certificate

## Supplementary Information to CE 633647

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Characteristics	Description	
<b>Product Name</b>	Atramat® PGLA90 Polyglactin 910 Poly(glycolide-co-L-lactide) Absorbable Surgical Sutures	
<b>Needle Characteristics</b>		
<b>Needle Description</b>	Premium, Fine, Heavy, Extra Heavy, Extra Heavy Loop, Premium Heavy, Premium Heavy Oval, Premium Regular, Premium Regular Oval, SUPRASHARP, ATRAGLIDE, SUPRAGLYDE, SUPRAGLYDE (Non Reflective), Regular.	
<b>Needle Type &amp; Codes</b>	Reverse Cutting	C, CE, K, KE, P, PE, PM, P-P, P-PE.
	Spatula	E, EA, EE, E-E, E-EA, E-EE.
	Spatula Ultima	EP.
	Taper Point	F, FE, G, GE, GH, R, RE, S, SB, SBE, SE, SG, SGE, SGH, SJ, SR, SRH, SRE, S-SG, S-SR, SV, SVE, X, XE, X-Loop, T, E-S, E-SE, CVSB, CVSBE, CVSV, CVSVE.
	Taper Cutting	PW, PWE, PWH, KW, W, WE, Y, YE, YJ, CVY, CVYE, CVYJ.
	Conventional Cutting	P-Q, P-QE, N, NE, Q, QE, QH.
	Cutting	PU, HP, HPE, U.
	Without Needle	SS, SS-C, EZ-SS.
	Blunt Point:	Z, ZE.
<b>Number of Needles</b>	1 or 2.	
<b>Needle Attribute</b>	Standard or Removable (PULL-OFF).	
<b>Needle Angle Range</b>	1/4, 3/8, 5/8, 1/2, J, STRAIGHT and BI-CURVE.	

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Characteristics	Description
<b>Needle Length Range</b>	6 mm (Min.) - 110 mm (Max.).
<b>Suture Thread Characteristics</b>	
<b>Absorbable/Non-Absorbable</b>	Absorbable.
<b>Suture Color</b>	Undyed or Violet.
<b>Suture Gauge Sizes (USP)</b>	6, 5, 4, 3, 2, 1, 0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0, 8-0 .
<b>Suture Length Range</b>	13 cm (Min.) - 300 cm (Max.).
<b>Quantity per Pouch</b>	1-20.
<b>Presentation</b>	1 suture type or one family.
	Kit (one code or different codes, one family or different families).
	Box with 6, 12, 24 or 36 pouches in Premium or Conventional Line.

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Page 3 of 4

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## Certificate History

Date	Reference Number	Action
30 November 2015	10154700	First issue. Transfer from another Notified Body and Renewal.
25 February 2019	8588105	Traceable to NB 0086.
Current	3060858	Certificate Renewal. Addition of a sterilization site, Proestéril, S.A de C.V. as a critical subcontractor for ETO sterilization for additional sterilization capacity. Change of sterilization chamber from Chamber #4 to Chamber #1 at Sterigenics. Administrative address change, Legal Manufacturer. Administrative address change, EU Rep. Addition of needle codes in the 'supplementary information' table of certificate.

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Page 4 of 4

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