

# EC Design-Examination Certificate

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

**No.****CE 633667**

## 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® PGA RAPID (Polyglycolic acid) Quick Absorption Surgical Suture**

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: **2015-11-29**Date: **2020-05-21**Expiry Date: **2024-05-26**

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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.  
This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 633667

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Characteristics	Description	
<b>Product Name</b>	<b>Atramat® PGA RAPID (Polyglycolic Acid) Quick Absorption Surgical Suture</b>	
<b>Needle Characteristics</b>		
Needle Description	Premium, Fine, Heavy, Extra Heavy, Extra Heavy Loop, Premium Heavy, Premium Heavy Oval, Premium Regular, Premium Regular Oval, SUPRASHARP, Regular, ATRAGLIDE, SUPRAGLYDE, SUPRAGLYDE (Non Reflective)	
Needle Type & Codes	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, 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, YB, YBE, Y, YV, YVE, YE, YJ, CVYB, CVYBE, CVY, CVYE, CVYV, CVYVE, 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.	
Number of Needles	1 or 2	
Needle Attribute	Standard or Removable (PULL-OFF)	
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, STRAIGHT and BI-CURVE	

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Characteristics	Description
Needle Length Range	6 mm (Min.) - 110 mm (Max.)
<b>Suture Thread Characteristics</b>	
Absorbable/Non-Absorbable	Absorbable
Suture Color	Undyed
Suture Gauge Sizes (USP)	6,5,4,3, 2, 1, 0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0, 8-0
Suture Length Range	15 cm (Min.) - 300 cm (Max.)
Quantity per Pouch	1-20
Presentation	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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## Certificate History

Date	Reference Number	Action
29 November 2015	10154723	First issue. Transfer from another Notified Body and Renewal.
22 June 2018	8944085	Re-instatement after suspension. Suspension Period: 23 October 2017 until the stated re-issue date.
25 February 2019	8588105	Traceable to NB 0086.
27 April 2020	3120096	Certificate Renewal. Administrative modification of the Manufacturer's address. Clarification of product prefixes in the 'supplementary information' table of the certificate.
Current	3215925	Administrative change, EU Rep address.

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