

# EC Design-Examination Certificate

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

**No.****CE 633645**

## 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® PGC25 Poly(glycolide-co-epsilon-caprolactone) 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: **2015-12-12**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 633645

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Characteristics	Description	
<b>Product Name</b>	Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) 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, S-SG
		S-SR, SGH, SJ, SR, SRE, SV, SVE, X, XE, X-Loop, T, CVS, CVSE, CVSB, CVSBE, E-S, E-SE
	Taper Cutting	PW, PWE, PWH, KW, W, WE, Y, YE, YJ, CVY, CVYE
	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	

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Characteristics		Description
<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	
<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>	2, 1, 0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0, 8-0	
<b>Suture Length Range</b>	15 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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## Certificate History

Date	Reference Number	Action
12 December 2015	10154699	First issue. Transfer from another Notified Body and Renewal.
25 February 2020	8588105	Traceable to NB 0086.
Current	3060693	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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