

EC Design-Examination Certificate

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

No. CE 633668
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® PDX (Polydioxanone) 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: **2015-11-29**

Date: **2020-07-23**

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.

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Supplementary Information to CE 633668

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Characteristics	Description	
Product Name	Atramat® PDX (Polydioxanone) Absorbable Surgical Sutures	
Needle Characteristics		
Needle Description	Premium, Fine, Heavy, Extra Heavy, Extra Heavy Loop, Premium Heavy, Premium Regular, Premium Regular Oval, SUPRASHARP, Regular, ATRAGLIDE, SUPRAGLYDE, SUPRAGLYDE (Non Reflective), Loop, Premium Loop Heavy.	
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
	Taper Point	F, FE, G, GE, GH, R, RE, S, SB, SBE, SE, SG, SGE, SGH, SR, SRE, S-SR, SV, SVE, X, XE, X-LOOP, XH-LOOP, E-S, E-SE, CVSB, CVSBE, CVSV, CVSVE
	Taper Cutting	PW, PW-LOOP, TW, 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
	Cutting	PU, HP, HPE, U
	Without Needle	SS, SS-C, EZ-SS
	Blunt Point:	Z, Z-LOOP
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.)
Suture Thread Characteristics	
Absorbable/Non-Absorbable	Absorbable
Suture Color	Undyed or Violet
Suture Gauge Sizes (USP)	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	1-8
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	10154724	First issue. Transfer from another Notified Body and Renewal.
25 February 2019	8588105	Traceable to NB 0086.
Current	3061077	Certificate Renewal. Addition of a sterilization site, Proestéiril, 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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