



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 12 0190 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws) certifies that the products – medical devices of Class III:

Absorbable Synthetic Surgical Sutures

Brand names: Cirugía Peruana, Vital Sutures, Sututex, Sutumed

(for detailed specification refer to the Annex, pages 1)

manufactured by company

UNILENE S.A.C.

Jr. NAPO N° 450 – BREÑA – LIMA 5 - PERU

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3 and 5, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803600679/2012, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **27th February 2017** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After receiving of the complementary EC Design-Examination Certificate approving the product design by the Notified Body No. 1023, and fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 28th February 2012



Paul Voj
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Annex to EC Certificate

No. 12 0190 QS/NB

Issued for the company:

UNILENE S.A.C., Jr. NAPO N° 450 – BREÑA – LIMA 5 - PERU

List of the medical devices covered by the Certificate:

Absorbable Synthetic Surgical Sutures with Needles:

Type	Length (cm)	Diameter (mm)	USP Size	Metric Size
POLYGLYCOLIC ACID POLYDIOXANONE POLYGLACTIN POLIGLECAPRONE	20 - 150	0.07- 0.099	6-0	0.7
		0.10-0.149	5-0	1
		0.15-0.199	4-0	1.5
		0.20-0.249	3-0	2
		0.30-0.339	2-0	3
		0.35-0.399	0	3.5
		0.40-0.499	1	4
		0.50-0.599	2	5

Needle Length (mm)	Needle Shape	Needle Type
5 - 75	Straight 1/2 Circle 1/8 Circle 3/8 Circle	Reverse Cutting Triangular Reverse Cutting Spatulated Taper Point



Paul Voj
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023