



Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC Design-Examination Certificate

## No. 12 0191 CN/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, Suturex, 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**

fulfil the essential requirements specified in the Annex I of the Directive 93/42/EEC relating to it, taking into account the product's intended use, as they are stated in the harmonized standards applied in conformity assessment procedures.

The Notified Body No. 1023 has executed the EC design-examination of the above-mentioned product according to the Annex II, paragraph 4, of the Directive 93/42/EEC. The detailed product descriptions, documents, assessment procedures and evaluation of the examination 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 design of the above referenced models of the medical devices.*
2. *It does not imply that the Notified Body has performed any surveillance or control of their manufacture.*
3. *The manufacturer is obligated to assure that all medical devices of the respective models conform to the type whose design has been approved by this Certificate.*
4. *The Certificate remains valid until the approved design is changed but until the 27<sup>th</sup> February 2017 at the latest.*
5. *After receiving of the complementary EC Certificate, confirming the manufacturer's quality system approval 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**



*Paul Voj*

**RNDr. Radomír Čevelík**

Representative of the Notified Body No. 1023

Issued in Zlín, on 28<sup>th</sup> February 2012





## Annex to EC Design-Examination Certificate

**No. 12 0191 CN/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



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