



Health Technology Certification

# EC-CERTIFICATE

## DESIGN EXAMINATION

This is to certify that the manufacturer

**CAMARK S.A.**

**INDUSTRIAL PARK AXIOUPOLI  
61400 AXIOUPOLI, GREECE**

for the design of

**Sterile Absorbable Surgical Sutures  
with or without needles**

**Certificate No:** 1145C03191101

**Issue Date:** 28/11/2019

**Original Approval:** 28/11/2019

**Valid until:** 27/05/2024

**Report No:** W002 1145 01 - 05  
W003 1145 01 - 05

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number 2803

conforms to the provisions of the Council Directive 93/42/EEC.

The certificate is based on the result of the examination of the submitted design dossier according to Annex II, Section 4, of the Directive. Any changes which could affect conformity with the essential requirements of Directive 93/42/EEC, or with the conditions prescribed for use of the product must receive further approval from HTCert. For marketing of the products, a Full Quality Assurance System Certificate according to the requirements of Annex II, Section 3, of Council Directive 93/42/EEC is required.

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director



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# Attachment to Certificate

No: 1145C03191101

Issued: 28/11/2019

Product(s)	Description
PGA	PGA synthetic absorbable sterile surgical sutures braided Variable length from 45cm to 180cm - Thread diameter from 4 to 7/0 (USP classification)
PGLA	PGLA synthetic absorbable sterile surgical sutures braided Variable length from 45cm to 150cm - Thread diameter from 2 to 7/0 (USP classification)
PGLA RAPID	PGLA RAPID synthetic absorbable sterile surgical sutures braided Variable length from 45cm to 150cm - Thread diameter from 2 to 6/0 (USP classification)
PDO	PDO synthetic absorbable sterile surgical sutures monofilament Variable length from 45cm to 150cm - Thread diameter from 2 to 7/0 (USP classification)
PGCL	PGCL synthetic absorbable sterile surgical sutures monofilament Variable length from 45cm to 150cm - Thread diameter from 2 to 6/0 (USP classification)

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director