



Health Technology Certification

EC-CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

CAMARK S.A.

INDUSTRIAL PARK AXIOUPOLI

61400 AXIOUPOLI, GREECE

for design, manufacturing and final testing of

Sterile Absorbable Surgical Sutures with or without needles

Certificate No: 1145C04191101

Issue Date: 28/11/2019

Original Approval: 28/11/2019

Valid until: 27/05/2024

References: W001 1145 01

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

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II (4) is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director



Health Technology Certification

Attachment to Certificate

No: 1145C04191101

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