



Health Technology Certification

# EC-CERTIFICATE

## FULL QUALITY ASSURANCE SYSTEM

This is to certify that the  
quality management system of

### Atlas Medical S.A.

28 C Miaouli Str., 153 44, Gerakas,  
Athens, Greece

Certificate No: **1193C04210101**  
Issue Date: **31/01/2021**  
Original Approval: **31/01/2021**  
Valid until: **26/05/2024**  
References: **W001 1193 01,**  
**W001 1193 02**

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

for design and manufacture of

### Sterile Absorbable and Non-Absorbable Surgical Sutures and Meshes.

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, Section 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

p. 1/2



Health Technology Certification



## Attachment to Certificate

No: 1193C04210101

Issued: 31/01/2021

### Products included:

#### Class III products

Absorbable Surgical Sutures	
Premisut PGA	Braided coated poly glycolic acid <i>Protas, dengan polyglykoloides sutures nilas</i>
Premisut PGAR	Braided coated short term Polyglycolic acid <i>sutures nilas</i>
Premisut PGLA	Braided coated Poly (Glycolide-Co-L - Lactide) / Polyglactin 910
Premisut PGLAR	Braided Coated Short Term Poly (Glycolide-Co-L- Lactide) /Polyglactin910
Premisut PGCL	Monofilament Poly (Glycolide CoCaprolactone)
Premisut PDO	Monofilament Poly (p-Dioxanone) <i>monofilament ini polidoksane no sutelas</i>
Non-Absorbable Surgical Sutures	
Premisut Polyester	Braided coated polyester
Premisut Polypropylene	Monofilament polypropylene
Premisut Nylon	Monofilament polyamide

#### Class IIb products

Non-Absorbable Surgical Sutures	
Premisut Silk	Braided coated silk <i>Protas, dengan silks nilas</i>
Premisut Steel Suture	Monofilament Stainless Steel 316 L
Non-Absorbable Surgical Meshes	
Premisut Regular Mesh	Monofilament Knitted Polypropylene Mesh
Premisut Lite Mesh	Monofilament Knitted Polypropylene Mesh

For and on behalf of HTCert

GEORGE PAPPOUS  
Managing Director

FILIPPOS KOTTIS  
Certification Director



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## DESIGN EXAMINATION

This is to certify that the  
quality management system of

### Atlas Medical S.A.

28 C Miaouli Str., 153 44, Gerakas,  
Athens, Greece

for design and manufacture of

### Sterile Absorbable and Non-Absorbable Surgical Sutures.

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

Certificate No: **1193C03210101**  
Issue Date: **31/01/2021**  
Original Approval: **31/01/2021**  
Valid until: **26/05/2024**  
References: **W002119301, W003119301,  
W002119302, W003119302**

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



## Attachment to Certificate

No: 1193C03210101

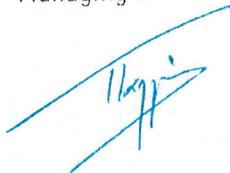
Issued: 31/01/2021

### Products included:

Products	Description
<b>Sterile Absorbable Surgical Sutures</b>	
Premisut PGA	Braided coated poly glycolic acid <i>Αντα, άνοδα, πολυγλυκόλις</i>
Premisut PGAR	Braided coated short term Polyglycolic acid <i>αυτή για αιώνα</i>
Premisut PGLA	Braided coated Poly (Glycolide-Co-L - Lactide) / Polyglactin 910
Premisut PGLAR	Braided Coated Short Term Poly (Glycolide-Co-L- Lactide) / Polyglactin 910
Premisut PGCL	Monofilament Poly (Glycolide CoCaprolactone)
Premisut PDO	Monofilament Poly (p-Dioxanone) <i>μονοφιλάντις, πολυδίοξανονς</i>
<b>Sterile Non-Absorbable Surgical Sutures</b>	
Premisut Polyester	Braided coated polyester
Premisut Polypropylene	Monofilament polypropylene
Premisut Nylon	Monofilament polyamide

For and on behalf of HTCert

GEORGE PAPPOUS  
Managing Director



FILIPPOS KOTTIS  
Certification Director

