



Health Technology Certification

EC-CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

SURGIMEDIC

104 - 106 A6 Industrial Zone,
10th of Ramadan, Sharkeya 44916, Egypt

for design and manufacture of

Sterile absorbable and non-absorbable surgical sutures with and without needles and sterile surgical meshes

Further details are given overleaf

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.

Certificate No: 1172C04210403
Issue Date: 28/04/2021
Original Approval: xx/04/2021
Valid until: 26/05/2024
References: W001 1172 02

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

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

p 1/2



Health Technology Certification

Attachment to Certificate

No: 1172C04210403

Issued: 28/04/2021

Products included:

Class III products

Absorbable Surgical Sutures	
SURCANONE	Sterile Absorbable polyester-poly (p-dioxanone) Sutures Monofilament, Coated, Violet with and without Needle
SURCAPRONE	Sterile Absorbable Poly Glycolide Co-Caprolactone Sutures Monofilament, Coated, Violet with and without Needle
SURCRYL	Sterile Polyglycolic Acid Synthetic Absorbable Surgical Sutures, Braided, Coated, Dyed Violet with and without Needle
SUTCRYL	Sterile Polyglactin 910 Synthetic Absorbable Surgical Sutures, Braided, Coated, Dyed Violet with Needle

Class IIb products

Non-Absorbable Surgical Sutures	
SURLON	Sterile Non Absorbable Nylon Sutures monofilament Black
SURLENE	Sterile Non Absorbable Polypropylene Sutures monofilament Blue
SURSILK	Sterile Non Absorbable Silk Sutures, Braided, Coated, Black
Non-Absorbable Surgical Meshes	
SURGIMESH PRO	Sterile Surgical Polypropylene Mesh

Certificate History

Issue date	Certificate Number	Reason for Issuance
27/10/2019	1172C04191001	First issuance
12/12/2019	1172C04191202	Addition of: SURCRYL, Polyglycolic Acid Sutures
28/04/2021	1172C04210403	Addition of: SURCANONE, Polyester- poly (p-dioxanone) Sutures SURCAPRONE, Poly Glycolide Co-Caprolactone Sutures SURLON, nylon sutures SURGIMESH PRO, Polypropylene Mesh

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

p 2/2