



Health Technology Certification

EC-CERTIFICATE

DESIGN EXAMINATION

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 surgical sutures with and
without needles**

Further details are given overleaf

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.

Certificate No: 1172C03210403
Issue Date: 28/04/2021
Original Approval: 27/10/2019
Valid until: 26/05/2024
References: W002117201/04/07/08
W003117201/04/07/08

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



Health Technology Certification

Attachment to Certificate

No: 1172C03210403

Issued: 28/04/2021

Products included:

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

Certificate History

Issue date	Certificate Number	Reason for Issuance
27/10/2019	1172C03191001	First issuance
12/12/2019	1172C03191202	Addition of SURCRYL, Polyglycolic Acid Sutures
28/04/2021	1172C03210403	Addition of: SURCANONE, Polyester- poly (p-dioxanone) Sutures SURCAPRONE, Poly Glycolide Co-Caprolactone Sutures

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director