



ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

EC CERTIFICATE FULL QUALITY ASSURANCE SYSTEM

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate.

The certificate is subject to terms and conditions overleaf.

Any significant changes in design or manufacture may render this certificate invalid.

Certificate Number: 301011861AD

This certificate is issued to replace certificate nr 301011861TN due to the addition of new products.

Manufacturer: **SMI AG**

Facility: **STEINERBERG 8, 4780 ST. VITH., BELGIUM.**

Products: **1. STERILE NON ABSORBABLE SURGICAL SUTURES.
2. STERILE ABSORBABLE SURGICAL SUTURES.
3. STERILE SURGICAL BLADES.
4. STERILE DISPOSABLE SKIN STAPLER.
5. STERILE DISPOSABLE SKIN STAPLE REMOVER.
6. STERILE SKIN MARKER.
7. STERILE SURGICAL POLYPROPYLENE MESHES.**

Brand names: **As in annex**


Devices Classification: **1. IIb, 2. III, 3. IIa, 4. IIa, 5. Is, 6. Is, 7. IIb.**

First issue date: **01/03/2021**

Current issue date: **25/05/2021**

Valid until: **24/05/2024**

Audit report: **200011861**


ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFThERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.
National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.



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ANNEX No. 301011861AD CERTIFICATE.

MEDICAL DEVICES	BRAND NAMES
<ul style="list-style-type: none">• <i>Classification IIb</i> <p>1. STERILE NON ABSORBABLE SURGICAL SUTURES.</p>	<ul style="list-style-type: none">• POLYPROPYLENE• POLYESTER• SILK• NYLON DACLON & SUPRAMID• STEEL
<ul style="list-style-type: none">• <i>Classification III</i> <p>2. STERILE ABSORBABLE SURGICAL SUTURES.</p>	<ul style="list-style-type: none">• SURGICRYL PGA• SURGICRYL MONOFILAMENT• SURGICRYL RAPID• SURGICRYL 910• SURGICRYL MONOFAST

TERMS & CONDITIONS

1. For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. 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.
3. For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. The certificate is valid only for the products and the facilities mentioned.
5. Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.

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