



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

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

EC CERTIFICATE DESIGN EXAMINATION

We hereby certify that a design examination has been carried out on the under mentioned devices according to Annex II section 4 of Directive 93/42/EEC and its transposition in Greek legislation.

The design of the devices conforms to the provisions of the Directive.

The certificate is based on the result of the examination of the design dossier.

Any changes in the approved design may render this certificate invalid.

Changes must immediately be reported to EKAPTY in order to receive further approval.

For marketing of the products a full quality assurance system certificate is required according to the requirements of Annex II 93/42/EEC (section 3).

Certificate Number: 301011861DE4

Manufacturer: **SMI AG**

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

Product: **STERILE SURGICAL SUTURE, *SURGICRYL 910* .**

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

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

Examination report: **200011861- Based on Technical File PH-15-H-SMI-05**


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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Certificate Number: 301011861DE3

Manufacturer: **SMI AG**

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

Product: **STERILE SURGICAL SUTURE, SURGICRYL MONOFAST .**

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

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

Examination report: **200011861- Based on Technical File- PH-16-I-SMI-05**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
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Certificate Number: 301011861DE6

Manufacturer: **SMI AG**

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

Product: **STERILE SURGICAL SUTURE, SURGICRYL MONOFILAMENT .**

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

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

Examination report: **200011861- Based on Technical File PH-13-H-SMI-05**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
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EC CERTIFICATE

DESIGN EXAMINATION

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Certificate Number: 301011861DE5

Manufacturer: **SMI AG**

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

Product: **STERILE SURGICAL SUTURE, SURGICRYL PGA.**

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

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

Examination report: **200011861- Based on Technical File PH-11-H-SMI-05**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
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Certificate Number: 301011861DE2

Manufacturer: **SMI AG**

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

Product: **STERILE SURGICAL SUTURE, SURGICRYL RAPID.**

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

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

Examination report: **200011861- Based on Technical File PH-14-H-SMI-00**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
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