

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: 301001521

Manufacturer: OMNIA SPA

Facility: VIA FRANCESCO DEL NEVO 190-FIDENZA PARMA ITALY

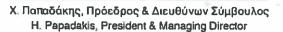
Products: AS LISTED IN ANNEX I

Devices Classification: AS LISTED IN ANNEX I

Current issue date: 26/07/2016

Valid until: 24/10/2017

Audit report: 200011321



Το Εθνικά 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. (ΕΚΑΡΤΥ) is a Notified body according to Council Directive 93/42/ΕΕC concerning medical devices, with identification number 0653.



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

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

ANNEX I No. 301001521 CERTIFICATE.

Classification IIb

1. NON ABSORBABLE SURGICAL SUTURES

1. SILK, POLYAMID

Classification III

1. ABSORBABLE SURGICAL SUTURES

1.1. PGA, MONOFAST

2. NON ABSORBABLE SURGICAL SUTURES

2.1. PTFE, POLYESTER

. Παπαδάκης, Πρόεδρος & Διευθύνων Σύμβουλος Η. Papadakis, President & Managing Director

TERMS & CONDITIONS

- For class I sterile products, 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 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.
- 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.